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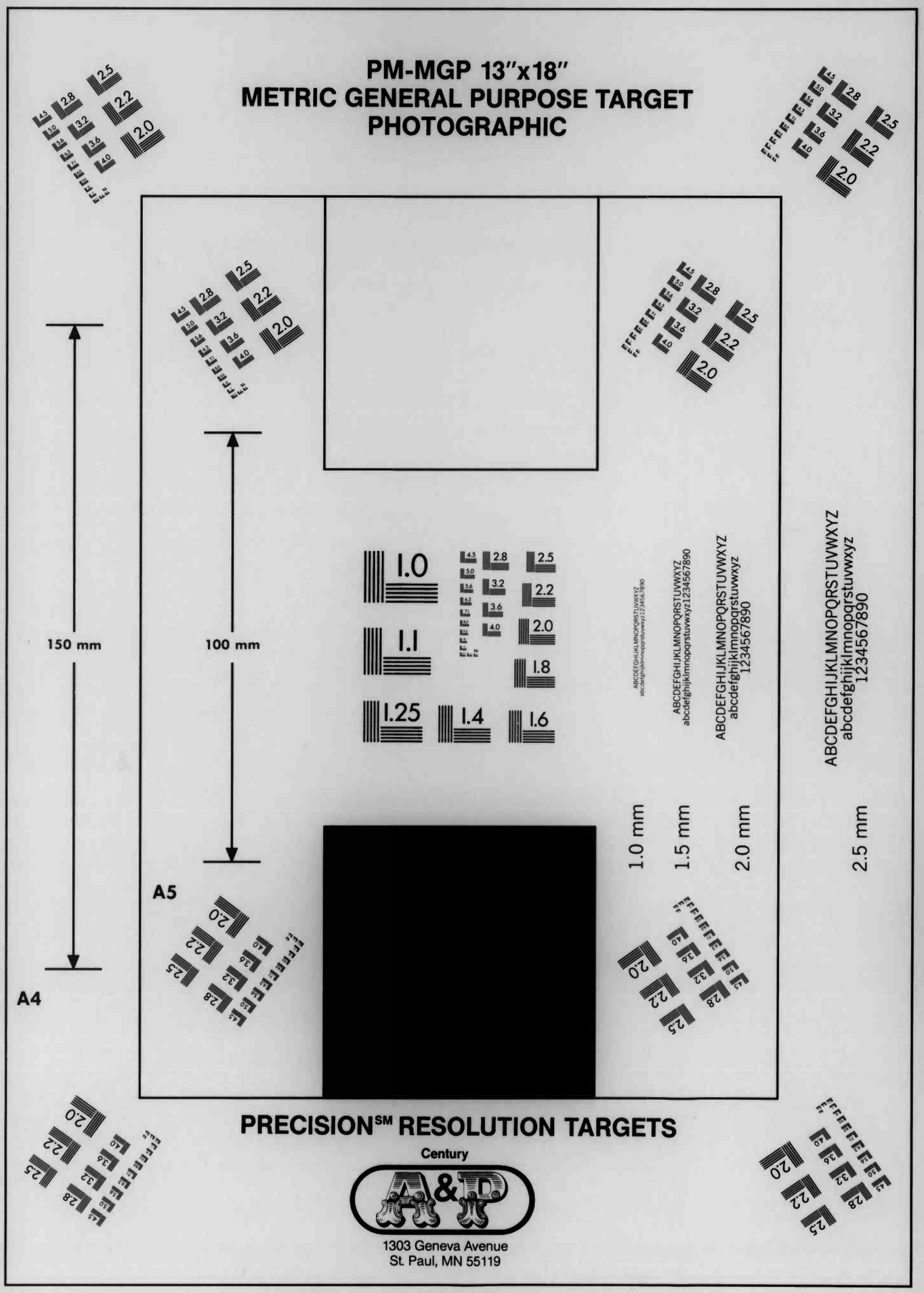

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FOODS, DRUGS, AND COSMETICS

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE UNITED STATES SENATE

SEVENTY-FOURTH CONGRESS

FIRST SESSION

ON

S. 5

A BILL TO PREVENT THE MANUFACTURE, SHIPMENT, AND SALE OF ADULTERATED OR MISBRANDED FOOD, DRINK, DRUGS, AND COSMETICS, AND TO REGULATE TRAFFIC THEREIN; TO PREVENT THE FALSE ADVERTISEMENT OF FOOD, DRINK, DRUGS, AND COSMETICS; AND FOR OTHER PURPOSES

MARCH 2, 8, AND 9, 1935

Printed for the use of the Committee on Commerce

UNITED STATES
GOVERNMENT PRINTING OFFICE
120089 WASHINGTON : 1935

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FOODS, DRUGS, AND COSMETICS

SATURDAY, MARCH 2, 1935

UNITED STATES SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to call, in the caucus room, Senate Office Building, at 10 a. m., to consider S. 5, Senator Clark presiding.

Present: Senators Clark (chairman), Copeland, Gibson.

Senator CLARK. The committee will come to order.

(The subcommittee have under consideration S. 5, with proposed amendments, which is here printed in full as follows:)

[Committee Print No. 3, Feb. 14, 1935]

[S. 5, 74th Cong., 1st Sess.]

[Omit the part struck through and insert the part printed in italic]

A BILL To prevent the manufacture, shipment, and sale of adulterated or misbranded food, drink, drugs, and cosmetics, and to regulate traffic therein; to prevent the false advertisement of food, drink, drugs, and cosmetics; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I

SECTION 1. That this Act may be cited as the "Federal Food, Drugs, and Cosmetic Act."

CHAPTER II

DEFINITION OF TERMS

~~SEC.~~ *SECTION* 201. As used in this Act, unless the context otherwise indicates—

(a) The term "food" includes all substances and preparations used for, or entering into the composition of, food, drink, confectionery, *chewing gum*, or condiment for man or other animals.

(b) The term "drug", for the purposes of this Act and not for the regulation of the legalized practice of the healing art, includes (1) all substances and preparations recognized in the United States Pharmacopœia, Homœopathic Pharmacopœia of the United States, or National Formulary, or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances, preparations, and devices, other than food, intended to affect the structure or any function of the body.

(c) The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

(d) The term "Territory" means any Territory or possession of the United States, including the District of Columbia.

(e) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce or manufacture within the District of Columbia or within any other territory not organized with a legislative body.

(f) The term "person" includes individual, partnership, corporation, and association.

(g) The term "Secretary" means the Secretary of Agriculture.

(h) The term "label" means the principal display or displays of written, printed, or graphic matter (1) upon any food, drug, or cosmetic, or the immediate container thereof, and (2) upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic.

(i) The term "labeling" includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any food, drug, or cosmetic.

(j) The term "advertisement" includes all representations of fact or opinion disseminated *to the public* in any manner or by any means other than by the labeling.

(k) The term "medical profession" means the legalized professions of the healing art; and the term "medical opinion" means the opinion, within their respective fields, of the practitioners of any branch of the ~~healing art~~ *medical profession*, the practice of which is licensed by law in the jurisdiction where such opinion is placed in issue in any proceeding under this Act.

(l) The term "official compendium" means the United States Pharmacopœia, Homœopathic Pharmacopœia of the United States, National Formulary, or any supplement thereto, official at the time any drug to which the provisions thereof relate is introduced into interstate commerce.

(m) The term "Department" means the Department of Agriculture of the United States.

(n) The term "Administration" means the Food and Drug Administration of the Department.

CHAPTER III

ADULTERATED FOOD

SECTION 301. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance prohibited *by section 304*, or in excess of the limits of tolerance prescribed by regulations as provided by sections 304, 701, and 703; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, *or if it is otherwise unfit for food;* or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, *or whereby it may have been rendered injurious to health;* or (5) if it is the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed of any poisonous or deleterious substance which may ~~by contamination~~ render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or create a deceptive appearance.

~~(d)~~ (c) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by sections 304, 701, and 703.

~~(e)~~ (d) If it is confectionery or ice cream ~~and~~ *it shall also be deemed to be adulterated if it* bears or contains any alcohol, resinous glaze, or nonnutritive substance except *harmless* coloring, flavoring, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery or ice cream by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing *harmless* nonnutritive masticatory substances.

MISBRANDED FOOD

SEC. 302. A food shall be deemed to be misbranded—

~~(d)~~ (a) If its labeling is false or misleading in any particular.

~~(a)~~ (b) If it is offered for sale under the name of another food.

~~(b)~~ (c) If it is an imitation of another food, and its label fails to bear, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

~~(c)~~ (d) ~~(1)~~ If its container is so made, formed, or filled as to mislead the purchaser~~, or (2) if its contents fall below the standard of fill prescribed by regulations as provided by sections 302, 701, and 703.~~

(e) If in package form it fails to bear a label containing: (1) The name and place of business of the manufacturer, packer, seller, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required on the label ~~to avoid adulteration or misbranding~~ under any provision of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily ~~intelligible to the~~ *understood by* purchasers and users of such articles under customary conditions of purchase and use, *due consideration being given to the size of the package.*

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by sections 303, 701, and 703, and (1) it fails to conform to such definition and standard, or (2) its label fails to bear the name of the food prescribed in the definition and standard, and if so required by such regulations when such definition and standard permits optional ingredients other than spices, flavors, and coloring, the common names of such optional ingredients as are present in such food.

~~(h) If it purports to be or is represented as a food for which a standard of quality has been prescribed by regulations as provided by sections 303, 701, and 703, and (1) its label fails to bears a statement of its quality in such terms as the regulations specify, or (2) its quality falls below such standard.~~

(h) If it purports to be or is represented as a food for which a standard of quality or fill of container has been prescribed by regulations as provided by sections 303, 701, and 703, and its quality or fill falls below such standard of quality or fill of container and its label fails to bear a statement, in such manner as the regulations specify, showing that it falls below such standard of quality or fill of container.

(i) If it is not subject to the provisions of paragraph (g) of this section and its label fails to bear (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients the common or usual name of each such ingredient ~~in order of predominance by weight~~; except that spices, flavors, and colorings, other than those sold as such, may be designated as spices, flavors, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of subdivision (2) of this paragraph is impracticable ~~because of normal variations in ingredients, or their quantities, usual to good manufacturing or packing practice,~~ exemptions ~~as to packages of assorted food~~ shall be established~~, and reasonable variations from the stated order of such ingredients shall be permitted, by regulations promulgated by the Secretary: *And provided further*, That exemption to compliance with the requirements of subdivision (2) of this paragraph is given to such foods where the common or usual name of each ingredient has been filed with the Secretary in accordance with regulations promulgated by him~~ *by regulations promulgated by the Secretary.*

(j) If it purports to be or is represented for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by regulations as provided by sections 701 and 703 statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value.

(k) If it bears or contains any artificial flavor, artificial color, or chemical preservative and it fails to bear a label stating that fact.

~~(k)~~ *(l)* The Secretary is hereby authorized to promulgate regulations exempting from any labeling ~~or packaging~~ requirements of this Act small open containers of fresh natural food and also food which is, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is in conformity with the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 303. For the effectuation of the purposes of this Act the Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, fixing and establishing for any food a definition and standard of identity, and a reasonable standard of quality ~~and~~ *and/or* fill of container: *Provided*, That no ~~standards~~ *standard* of quality shall be established for *any* fresh natural ~~foods~~ *food.*

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

~~SEC. 304. (a) If an added poisonous or added deleterious substance in or on food is or may be injurious to health, the Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, prohibiting such added substance in or on any food, or establishing tolerances limiting the amount therein or thereon, for the protection of public health, taking into account the extent to which the use of such substance is required in the production of such food and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.~~

SEC. 304. (a) *To safeguard the public health, no poisonous or deleterious substance shall be added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice; but when such substance is so required or cannot be so avoided, the Secretary is authorized, for the protection of public health, to promulgate regulations, as provided by sections 701 and 703, limiting the quantity therein or thereon. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.*

(b) The Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, for the certification of coal-tar colors which are harmless and suitable for use in food.

~~PERMIT~~ ~~FACTORIES~~ *EMERGENCY PERMIT CONTROL*

SEC. 305. (a). Whenever the Secretary finds that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof, be injurious to health, and such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he is then, and in such case only authorized to promulgate regulations, as provided by sections 701 and 703, governing the conditions of manufacture, processing, or packing for such temporary periods of time as may be necessary to protect the public health, and requiring manufacturers, processors, and packers of such class of articles to hold permits conditioned on compliance with such regulations.

(b) The Secretary is authorized to issue such permits for such periods of time as he may by regulations prescribe and to make regulations governing the issuance and renewal thereof. The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. ~~The Secretary shall reinstate the permit whenever, after hearing and an inspection of the establishment, it is found that adequate measures have been taken~~ *The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken* to comply with and maintain the conditions of the ~~original~~ permit, *as originally issued.*

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

CHAPTER IV

ADULTERATED DRUGS

SECTION 401. A drug shall be deemed to be adulterated—

~~(a) If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.~~

(a) (1) If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof; or (2) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or (3) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (4) if its container is composed of any poisonous or deleterious substance which may render it injurious to health; or (5) if it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by sections 403, 701, and 703.

(b) If its name is ~~the same as or simulates a name~~ recognized in an official compendium, or if its purports to be a drug the name of which is so recognized, and it ~~(1) fails to meet the definition and descriptions set forth therein or (2)~~ differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth therein; except that whenever tests or methods of assay have not been prescribed therein, or such tests or methods of assay as are prescribed are insufficient, for determining whether or not such drug complies with such standard, the Secretary is hereby authorized to bring such fact to the attention of the appropriate body charged with the revision of such compendium and if such body fails within a reasonable time to prescribe tests or methods of assay which are sufficient, then the Secretary may prescribe for the purposes of this Act such tests or methods of assay by regulations as provided by sections 701 and 703. No drug shall be deemed to be adulterated under this paragraph because it differs from the standards of strength, quality, or purity therefor set forth in an official compendium, if its label bears in juxtaposition with the name of the drug a statement indicating wherein its strength, quality, and purity, as determined by the tests or methods of assay applicable under this paragraph, differ from the standards therefor set forth in such compendium. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it it labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its identity or strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS

SEC. 402. A drug shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular *of* such representation *it* is not sustained by demonstrable scientific facts or substantial medical opinion.

(b) If in package form it fails to bear a label containing: (1) The name and place of business of the manufacturer, packer, seller, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required on the label ~~to avoid adulteration or misbranding~~ under any provision of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily ~~intelligible to the~~ *understood by* purchasers and users of such articles under customary conditions of purchase and use. *due consideration being given to the size of the package.*

(d) If it is for internal use by man and contains any quantity of any of the following narcotic or hypnotic substances: Alpha eucaine, ~~barbital~~ *barbituric acid,* beta eucaine, bromal, canabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphonnethane, or any *habit forming* narcotic or hypnotic substance chemically derived therefrom, or any other narcotic or hypnotic substance which has been designated as habit forming by regulations as provided by sections 701 and 703, and its label fails to bear the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

(e) If it is not designated solely by a name recognized in an official compendium and its label fails to bear (1) a common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients the ~~names and quantity or proportion~~ *name* of each active ingredient: ~~*Provided,* That exemption to compliance with subdivision (2) of this paragraph is given in such cases where the name, quantity, and proportion of each active ingredient is filed with the Secretary in accordance with regulations promulgated by him.~~

(f) If its labeling fails to bear plainly and conspicuously (1) complete and ~~explicit~~ *adequate* directions for use, and (2) such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 703, against use in such pathological conditions or by children where its use ~~is contraindicated and~~ may be dangerous to health, or against unsafe dosage or methods or duration of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by sections 701 and 703, exempting such drug from such requirement.

(g) If its name is ~~the same as, or simulates, a name~~ recognized in an official compendium, *or if it purports to be a drug the name of which is so recognized*, and it is not packaged and labeled as prescribed therein. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not to those of the United States Pharmacopœia.

(h) If it has been designated by regulations, as provided by sections 701 and 703, as a drug liable to deterioration, and is not packaged in such form or manner, or its label fails to bear a statement of such precautions, as such regulations require for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If its container is so made, formed, or filled as to mislead the purchaser; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the body and its labeling fails to bear a plain and conspicuous statement of such use, including the strength or dilution, manner, and duration of application, and when tested by a standard method, it does not have the germicidal effect *in the strength or dilution and* within the duration so prescribed of a one to eighty dilution of phenol used by a standard ~~testing~~ method for ten minutes at thirty-seven degrees centrigrade. All ~~testing~~ *standard* methods for the purposes of this paragraph shall be prescribed by regulations as provided by sections 701 and 703: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical professions, or appears only in scientific publications of these professions.

(k) If it purports to be or is represented as an inhibitory antiseptic for any use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body, and its labeling fails to bear a plain and conspicuous statement of such use, including strength or dilution, ~~and~~ manner, *and duration* of application, and when tested by a standard method~~, it fails~~ *for determining inhibitory antiseptic effect, it fails, in the strength or dilution prescribed*, to prevent the growth of micro-organisms within the entire time of ~~such~~ duration *prescribed*. All ~~testing~~ *standard* methods for the purposes of this paragraph shall be prescribed by regulations as provided by sections 701 and 703: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical profession, or appears only in scientific publications of these professions.

(l) The Secretary is hereby authorized to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs are in conformity with the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

SEC. 403. The Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, for the certification of coal-tar colors which are harmless and suitable for use in drugs.

CHAPTER V

ADULTERATED COSMETICS

SECTION 501. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to ~~the user~~ *health* under the conditions of use prescribed in the labeling *or advertising* thereof, or under such conditions of use as are customary or usual.

~~(b) If it bears or contains any poisonous or deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulations as provided by sections 502, 701, and 703.~~

(b) It it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby if may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed of any poisonous or deleterious substance which may render it injurious to health.

(e) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by sections 503, 701, and 703.

MISBRANDED COSMETICS

SEC. 502. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form it fails to bear a label containing: (1) The name and place of business of the manufacturer, packer, seller, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under subdivision (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages *and soap* shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required on the label ~~to avoid adulteration or misbranding~~ under any provision of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily ~~intelligible~~ *to understood by* the purchasers and users of such articles under customary conditions of purchase and use, *due consideration being given to the size of the package.*

(d) The Secretary is hereby authorized to promulgate regulations exempting from any labeling ~~or packaging~~ requirement of this Act cosmetics which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are in conformity with the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

~~TOLERANCES FOR POISONOUS INGREDIENTS IN COSMETICS~~

~~SEC. 503. (a) If a poisonous or deleterious substance in cosmetics is or may be injurious to health, the Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, prohibiting such substance in or on any cosmetic, or establishing tolerances limiting the amount therein or thereon, for the protection of public health, taking into account the extent to which the use of such substance is required in the production of such cosmetic and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.~~

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 503. The Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, for the certification of coal-tar colors which are harmless and suitable for use in cosmetics.

CHAPTER VI

FALSE ADVERTISEMENT

SECTION 601. (a) An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any particular relevant to the purposes of this Act regarding such food, drug, or cosmetic. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every

particular *of* such representation *it* is not sustained by demonstrable scientific facts or substantial medical opinion.

~~(b) It shall be unlawful to advertise for sale in interstate commerce a drug represented to have any therapeutic~~

(b) *For the purposes of this Act the advertising of a drug for sale in interstate commerce, representing it to have any therapeutic* effect in the treatment of cancer, tuberculosis, venereal diseases, heart and vascular diseases, as well as any other disease *perilous to the life of the individual or to the public health* which may be added to this list by regulations as provided by sections 701 and 703, *shall be deemed to be false;* except that no advertisement not in violation of paragraph (a) of this section shall be deemed to be false under this paragraph if it is disseminated only to members of the medical and pharmaceutical professions or appears only in the scientific periodicals of these professions, or ~~if it~~ is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs.

Chapter VII

General Administrative Provisions

POWER TO MAKE REGULATIONS

Sec. 701. (a) The authority to ~~make~~ *promulgate* regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 714, *except as otherwise provided therein.* Such regulations shall be promulgated in such manner and take effect at such time as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

COURT REVIEW OF REGULATIONS AND ADMINISTRATIVE ACTIONS

Sec. 702. The district courts of the United States are hereby vested with jurisdiction, on complaint of any interested person, (*1*) to restrain by injunction, temporary or permanent, the enforcement by any officer, representative, or employee of the Department ~~of Agriculture~~ of any regulation promulgated as provided in sections 701 and 703 if it is shown that the regulation is unreasonable, arbitrary, or capricious, *in the light of the facts* or not in accordance with law, and that the petitioner ~~will~~ *may* suffer substantial damage by reason of its enforcement: ~~*Provided* That nothing in this section shall be deemed to abridge the right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this Act, or who shall intervene as claimant in any proceeding of libel for condemnation to plead that the regulation whose violation is alleged as the ground for such prosecution, suit, or libel is invalid on any of the grounds set forth above;~~ *and* (*2*) *to grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the Department in the administration of this Act, if it has been shown that such act or omission is unreasonable, arbitrary, or capricious, in the light of the facts, or not in accordance with law, and that the petitioner may suffer substantial damage thereby: Provided, That nothing in this section shall be deemed to abridge the right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this Act, or who shall intervene as claimant in any proceeding of libel for condemnation to plead that the regulation, the violation of which is alleged as the ground for such prosecution, suit, or libel, is invalid on any of the grounds set forth above.*

PUBLIC HEALTH AND FOOD STANDARDS COMMITTEES

Sec. 703. (a) To aid and advise the Secretary in promulgating regulations for the protection of public health, as contemplated by section 301, paragraphs (a) and ~~(d)~~ (*c*); ~~section 401, paragraph (b); section 501, paragraph (b); section 302, paragraph (j); section 402, paragraphs (d), (f), (h), (j), and (k); sections 304, 305, 503, and section 601, paragraph (b)~~ *section 302, paragraph (j); section 304, paragraphs (a) and (b); section 305, paragraph (a); section 401, paragraphs (a) and (b); section 402, paragraphs (d), (f), (h), (j), and (k); section 403; section 501, paragraph (c); section 503; and section 601, paragraph* (*b*), a Committee on Public Health is hereby provided which shall consist of five members designated by the President with a view to their distinguished scientific attainment and interest in public health *with respect to food, drugs, and/or cosmetics* and without regard to their political affiliation.

(b) To aid and advise the Secretary in the promulgation of regulations with respect to food, as contemplated by section 302, paragraphs ~~(c),~~ (g) and (h); and section 303, a Committee on Food Standards is hereby provided which shall consist of seven members, three of whom shall be selected from the public, two from the food producing, processing, manufacturing, and distributing industry, and two from the ~~Food and Drug~~ Administration. The members selected from the public and the food industry shall be appointed by the President without regard to political affiliation, and the members from the ~~Food and Drug~~ Administration shall be designated by the Secretary.

(c) Whenever the Secretary deems that any regulation contemplated by the provisions of this Act enumerated in paragraphs (a) and (b) of this section should be established, he shall so advise the appropriate committee. With the approval of a majority of its members, the committee shall recommend to the Secretary a proposed regulation, and the Secretary shall give notice of the proposal and of the time and place of a public hearing to be held thereon not less than thirty days after the date of such notice. After such hearing the Secretary is authorized ~~to make findings of fact and~~ to formulate and promulgate such regulation, but no such regulation shall be promulgated without the approval of a majority of the members of the committee. The regulation so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to ninety days after its promulgation, and may be amended or repealed in the same manner as is provided for its adoption: *Provided,* That regulations setting up exemptions pursuant to section 402, paragraph (f), may be promulgated without notice or hearing and shall become effective at such time as the Secretary determines.

(d) If any regulation promulgated by the Secretary ~~under section 301, paragraphs (a) and (d); section 501, paragraph (b); section 402, paragraphs (j) and (k); and sections 304 and 503~~ *under section 301, paragraphs (a) and (c); section 302, paragraph (j); section 304, paragraphs (a) and (b); section 401, paragraph (a); section 402, paragraphs (d), (h), (j), and (k); section 403; section 501, paragraph (e); and section 503,* is declared invalid in any court proceeding, the Secretary may promulgate in substitution therefor a temporary regulation consistent with such decision. Such temporary regulation may be promulgated without notice or hearing and shall become effective at and for such time as the Secretary designates, but in no event longer than one hundred and eighty days from the effective date thereof. On or before the promulgation of such temporary regulation the Secretary shall institute proceedings, as provided in paragraph (c) of this section, for the establishment of a new regulation.

(e) The term of office of members of the committees provided by paragraphs (a) and (b) of this section, other than members from the ~~Food and Drug~~ Administration, shall be five years; except that an appointment to fill a vacancy occurring before the expiration of a term shall be for the remainder of that term, and of the appointments first made to each committee after approval of this Act, one shall be for one year, one for two years, one for three years, and one for four years, as shall be designated by the President in their respective appointments. The President shall designate the chairmen of the committees. No person who is a member of the Department ~~of Agriculture~~ or who has a financial interest in the manufacture, advertising, or sale of any food, drug, or cosmetic shall be eligible to serve on the Committee on Public Health, or as a member from the public on the Committee on Food Standards.

(f) Each committee shall convene at the call of its chairman at such time and place as he may designate, but action by either committee under this section may be taken by the members thereof acting individually without convening in meeting. In each case in which approval by either committee of a regulation is required under this section, the Secretary shall transmit to each member of such committee a transcript of the record of the public hearing held by him. Members of the committees shall be given due notice of, and may sit with the Secretary or his representatives at, all such public hearings relating to the functions of their respective committees. Each committee on its own motion or at the request of the Secretary may advise him of its views on any question concerning the enforcement of this Act.

ADVISORY COMMITTEES FROM INDUSTRIES

SEC. 704. For the purposes of consultation in formulating general administrative policies for the enforcement of this Act, the Secretary is authorized to appoint an advisory committee from each of the following groups: The food industry, the drug industry, the cosmetic industry, *creators or* disseminators of advertising, the public. To aid in securing compliance with the requirements of this Act, the Secretary is further authorized to accept plans for such self-regulation of advertising *or trade* practices as tend to effectuate the purposes of this Act, when presented by associations or groups representative of their industries: *Provided*, That nothing in this paragraph shall be construed as restricting the responsibilities and powers conferred upon the Secretary by this Act, and no plans shall be accepted which are designed to promote monopolies or eliminate or oppress legitimate enterprise.

EXAMINATIONS AND INVESTIGATIONS

SEC. 705. The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department ~~of Agriculture~~ or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary.

RECORDS OF INTERSTATE SHIPMENT

SEC. 706. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, or cosmetics in interstate commerce, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, or cosmetic, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a definite statement in writing specifying the nature or kind of food, drug, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the *other* provisions of this Act by reason of their receipt, carriage, or delivery of food, drugs, cosmetics or advertising matter in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 707. (a) In order adequately to ~~regulate interstate commerce in food, drugs, and cosmetics, and enforce~~ *protect public health and welfare through enforcement of* the provisions of this Act, officers or employees duly designated by the Secretary, after first making reasonable request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed,or held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, finished and unfinished materials, containers, and labels there used or stored.

(b) ~~The~~ *In order adequately to protect public health and welfare, the* several district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, the shipment in interstate commerce or delivery after receipt in interstate commerce of any food, drug, or cosmetic from or by any factory, warehouse, establishment, or vehicle, designated in paragraph (a) of this section if the owner, operator, or custodian thereof has, after reasonable request, denied permission to officers or employees duly designated by the Secretary so to enter and inspect such factory, warehouse, establishment, or vehicle and equipment, finished and unfinished materials, containers, and labels there used or stored. Whenever such permission is granted, the injunction issued pursuant to this paragraph shall be dissolved, or may be continued in force subject to such conditions governing the inspection as the court may order. Violation of any injunction issued pursuant to this paragraph may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney.

PROHIBITED ACTS AND PENALTIES

SEC. 708. (a) The following ~~Acts~~ *acts and the causing thereof* are hereby prohibited:

(1) The introduction *or delivery for introduction* into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, or cosmetic in interstate commerce.

(3) The receipt in interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

(4) The dissemination of any false advertisement by ~~radio broadcast,~~ United States mails, or in interstate ~~commerce,~~ *commerce by radio-broadcast or otherwise*, for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics.

(5) The dissemination of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics in interstate commerce.

(6) The introduction into interstate commerce of any food~~, drug, or cosmetic~~ if the manufacturer, processor, or packer does not hold an unsuspended valid permit when so required by regulations under section 305.

(7) The refusal to permit access to or copying of any record as required by section 706.

(8) The forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 305.

(9) The using by any person to his own advantage, or revealing, other than to the Secretary or his officers or employees or to the courts when relevant in the trial of any case under this Act, any information acquired under authority of sections 305 or 707 concerning any method or process which as a trade secret is entitled to protection.

(b) Any person who violates ~~or causes to be violated~~ any of the provisions of *subdivision (1) to (7), inclusive, of* paragraph (a) of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not ~~less than $100 nor~~ more than $1,000, or both such imprisonment and fine; and for a second or subsequent offense imprisonment for not more than two years, or a fine of not ~~less than $100 nor~~ more than $3,000 or both such imprisonment and fine.

(c) Notwithstanding the provision of paragraph (b) of this section, in case of a willful ~~offense~~ *violation of any of the provisions of subdivisions (1) to (7), inclusive, of paragraph (a) of this section* the penalty shall be imprisonment for not more than three years, or a fine of not ~~less than $1,000 nor~~ more than $10,000, or both such imprisonment and fine.

~~(d) No publisher, radio-broadcast licensee, or other agency or medium for the dissemination of advertising shall be deemed to have violated the provisions of paragraphs (b) or (c) of this section by reason of the dissemination of any false advertisement, but the liability shall rest upon the manufacturer, packer, distributor, or seller who caused the dissemination of such advertisement. Any publisher, radio-broadcast licensee, or other agency or medium for the dissemination of advertising, who, on reasonable request of any officer or employee duly designated by the Secretary, willfully refuses to furnish the name and post-office address of the person who caused him to disseminate any advertisement; or who disseminates any false advertisement where the dissemination thereof has been caused by a person residing in a foreign country, and does not establish a guarantee or undertaking signed by a manufacturer, packer, distributor, or seller of the article advertised, residing in the United States, to the effect that such person assumes full responsibility for any violation of this Act incurred by the dissemination of such advertisement; shall be guilty of a misdemeanor and shall on conviction thereof be subject to the penalties prescribed in paragraph (c) of this section.~~

(d) No publisher, radio-broadcast licensee, advertising agency, or other agency or medium for the dissemination of advertising shall be deemed to have violated the provisions of subdivision (4) or (5) of paragraph (a) of this section by reason of the dissemination of any false advertisement when such dissemination is caused by the manufacturer, packer, distributor, or seller, residing in the United States, of the article so advertised; but such manufacturer, packer, distributor, or seller shall be amenable to the prosecution and penalties provided for violation of such subdivisions.

It shall be unlawful for any publisher, radio-broadcast licensee, advertising agency, or other agency or medium for the dissemination of advertising willfully to refuse, on reasonable request of an officer or employee duly designated by the Secretary, to furnish to such officer or employee the name and post-office address of the manufacturer, packer, distributor, or seller, residing in the United States, who caused him to disseminate any advertisement; and any publisher, radio-broadcast licensee, advertising agency, or other agency or medium for the dissemination of advertising who so refuses shall be guilty of a misdemeanor and shall on conviction thereof be subject to the penalties prescribed by paragraph (b) of this section.

(e) No dealer shall be ~~prosecuted under~~ *subject to the penalties of* paragraph (b) of this section (1) for having received in interstate commerce ~~an~~ *any* article *of food drug, or cosmetic* and in good faith sold it as received unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and all documents pertaining to the delivery of the article to him, or (2) if he establishes a guaranty or undertaking signed by the person residing in the United States from whom he received in good faith the article of food, drug, or cosmetic, or the advertising copy therefor, to the effect that such ~~person assumes full responsibility for any violation~~ *article is not adulterated or misbranded, and such copy is not false, within the meaning* of this Act, designating it, ~~which may be incurred by the introduction of such article into interstate commerce or by the dissemination of such advertising.~~ To afford protection, such guaranty or undertaking shall contain the name and address of the person furnishing such guaranty or undertaking, and such person shall be amenable to the prosecution and penalties which would attach in due course to the dealer under the provisions of this Act. No retail dealer shall be prosecuted under this section for the dissemination, in good faith, other than by radio broadcast of any advertisement offering for sale at his place of business any article which is not distributed or sold in interstate commerce *by him or others.*

~~(f) Any person who forges, counterfeits, simulates or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 305, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.~~

~~(g) Any person who uses to his own advantage or reveals, other than to the Secretary or his officers or employees, or to the courts when relevant in the trial of any case under this Act, any information acquired under authority of sections 305 or 707, concerning any method or process which is entitled to protection in equity as a trade secret, shall be guilty of a felony, and shall on conviction thereof be subject to imprisonment for not more than two years or a fine of not more than $5,000 or both such imprisonment and fine.~~

(f) Any person who violates any of the provisions of subdivision (8) of paragraph (a) of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not more than $5,000, or both such imprisonment and fine.

(g) Any person who violates any of the provisions of subdivision (9) of paragraph (a) of this section shall be guilty of a felony and shall on conviction thereof be subject to imprisonment for not more than two years or a fine of not more than $5,000, or both such imprisonment and fine.

LIABILITY OF CORPORATIONS AND THEIR OFFICERS

SEC. 709. (a) When construing and enforcing the provisions of this Act, *unless otherwise provided*, the act, omission, or failure of any officer, employee, or agent acting for or employed by any person, within the scope of his employment or office, shall in every case be deemed to be the act, omission, or failure of such person, as well as that of the officer, employee, or agent.

(b) Whenever a corporation or association violates any of the provisions of this Act, *unless otherwise provided*, such violation shall also be deemed to be a violation by the individual directors, officers, or agents of such corporation or association who personally ordered, or did any of the acts constituting, in whole or in part, such violation.

INSTITUTION OF CRIMINAL PROCEEDINGS

SEC. 710. The Secretary shall, before reporting any violation of this Act to any United States attorney for institution of criminal proceedings thereunder, afford due notice and opportunity for hearing to interested persons in accordance with such regulations as the Secretary shall prescribe. ~~(b) The report of the Secretary to the United States attorney for the institution of criminal proceedings under this Act~~ *The report* shall be accompanied by findings of the appropriate officers and employees, duly authenticated under their oaths. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings minor violations of this Act whenever he believes that the purpose of the Act can best be accomplished by a suitable notice or warning.

SEIZURE

SEC. 711. (a) Any *article of* food, drug, or cosmetic ~~in interstate commerce~~ that is adulterated or misbranded *when introduced into or while in interstate commerce*, or that has been manufactured, processed, or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold an unsuspended valid permit, if so required by regulations under section 305, shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. ~~The article shall be liable to seizure (1) by process pursuant to the libel, or (2) if a chief of station or other officer of the Food and Drug Administration, duly designated by the Secretary, has probable cause to believe that the article is so adulterated as to be imminently dangerous to health, then, and in such case only, by order of such officer, issued under his oath of office, particularly describing the article to be seized, the place where located, and the officer or employee to make the seizure. In case of seizure pursuant to any such order, the jurisdiction of the court shall attach upon such seizure. Any article seized pursuant to any such order shall thereupon be promptly placed in the custody of the court and a libel of information shall be promptly filed for condemnation thereof; and if the court before which the condemnation proceedings are had shall find that there was probable cause for such seizure, it shall issue a certificate of probable cause.~~ *The article shall be liable to seizure by process pursuant to the libel; but if a chief of station or other employee of the Administration, duly designated by the Secretary, has probable cause to believe that such article is so adulterated as to be imminently dangerous to health, then, and in such case only, the article shall be liable to seizure by such chief of station or employee, who shall promptly report the facts to the proper United States attorney. Such United States attorney shall file a libel of information for condemnation of the article so seized. If the court in which the libel was filed shall find that there was probable cause for such seizure, it shall issue a certificate of probable cause.*

(b) If, in any proceeding against any *chief of station or other* officer or employee by reason of a seizure pursuant to paragraph (a)~~, subdivision (2)~~ of this section, the court shall find that there was probable cause for the seizure, or if a certificate of probable cause has been issued in the condemnation proceedings, then, in the event of a judgment against such officer or employee, the amount thereof shall, upon final judgment, be paid out of appropriations made for the administration of this Act.

(c) The court ~~shall, by order at any~~ *at any time after seizure up to a reasonable* time before trial, *shall by order* allow any party to a condemnation proceeding to obtain a representative sample of the article seized.

(d) Any food, drug, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory *in which sold*, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the party obtaining release of the article under bond. Any article condemned by reason of the manufacturer, processor, or packer not holding an unsuspended valid permit when so required by regulations under section 305 shall be disposed of by destruction.

(e) The proceedings in cases under this section shall conform, as nearly as may be, to the proceedings in admiralty; except that either party may demand trial by jury of any issue of fact joined in any such case. *In cases of articles of food, drugs, or cosmetics seized under the provisions of this section when the same issues of adulteration or misbranding under the provisions of this Act, raised by the same claimant, are pending in various jurisdictions, the United States District Court for the district where one of such seizures is pending which is nearest to the place of business of such claimant is hereby vested with jurisdiction to try such cases separately: and on application of the claimant, seasonably made, may be tried in such jurisdiction. Separate verdicts shall be rendered in each case and judgments entered on such verdicts in conformity with the provisions of this section.*

(f) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

~~(g) To avoid multiplicity of libel for condemnation proceedings without impairing the protection of the public or the opportunity for the prompt trial on the merits of alleged violations, the district courts of the United States are hereby vested with jurisdiction to restrain by injunction, as hereinafter provided, the institution of more than three seizure actions under this section against any article if (1) the alleged violation is one of misbranding only, (2) all current shipments of the article alleged to be misbranded bear the same labeling, (3) such alleged misbranding does not involve danger to health or gross deception, and (4) such misbranding has not been the basis of a prior judgment in favor of the United States in any criminal prosecutions or libel for condemnation proceeding under this Act. Upon motion by claimant of any article seized under this section, the court may order the dismissal of the libel for condemnation thereof if more than three seizure actions have previously been instituted against such article and such claimant would be entitled to injunctive relief as hereinbefore provided.~~

~~(h) Any injunction issued pursuant to paragraph (g) of this section shall be dissolved on motion of the United States attorney, (1) upon the presentation by him of a duly certified judgment of condemnation in a seizure case against such article, or (2) at the expiration of the term of court next ensuing after the term in which such injunction issued, unless the complainant files with the court a duly certified judgment rendered upon a determination of the issue of misbranding, and entered pursuant to this section after the issuance of such injunction, or evidence satisfactory to the court of his inability to secure such determination.~~

(g) The several district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, any multiplicity of proceedings under this section with respect of any food, drug, or cosmetic, for cause shown which is satisfactory to the court and consistent with the purpose of this Act. Such injunction shall contain any conditions deemed by the court to be necessary in the circumstances.

INJUNCTION PROCEEDINGS

SEC. 712. (a) In order to avoid multiplicity of criminal prosecutions or libel for condemnation proceedings, the district courts of the United States are hereby vested with jurisdiction *for cause shown*, to restrain by injunction, temporary or permanent, any person from the repetitious (1) introduction *or causing to be introduced* into interstate commerce of any adulterated or misbranded food, drug, or cosmetic; or (2) dissemination *at subsequent intervals of time and within the advertiser's control of repetition* of *or causing to be disseminated* any false advertisement by ~~radio broadcast~~, United States mails, or in interstate commerce *by radio-broadcast or otherwise*, for the purpose of inducing, directly or indirectly, the purchase of food, drugs, or cosmetics; or (3) dissemination of *or causing to be disseminated* a false advertisement by any means for the purpose of inducng, directly or indirectly, the purchase of food, drugs, or cosmetics in interstate commerce. In such injunction proceedings it shall not be necessary to show on the part of such person an intent to continue the offense.

(b) Violation of any injunction issued pursuant to this section may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney; and process of the court for the arrest of the violator may be served at any place in the United States or subject to its jurisdiction.

DUTIES OF UNITED STATES ATTORNEY

SEC. 713. It shall be the duty of each United States attorney to whom the Secretary reports any violation for institution of criminal, libel of *information* for condemnation, or other proceedings under this Act, or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violation, to cause appropriate proceedings to be instituted in the proper courts of the United States without delay. All suits instituted under this Act other than those pursuant to section 711, paragraph (g), and section 702 shall be by and in the name of the United States.

IMPORTS AND EXPORTS

SEC. 714. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture upon his request, samples of food, drugs, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) any false advertisement of such article has been disseminated in the United States by the importer or exporter thereof, or any person in privity with him, within three months prior to the date such article is offered for import, or (2) such article has been manufactured, processed, or packed under insanitary conditions, or (3) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (4) such article is adulterated or misbranded, then such article shall be refused admission.

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon, and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, or cosmetic intended for export shall not be deemed to be adultered or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) complies with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package with the words "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this Act.

PUBLICITY

SEC. 715. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated ~~such~~ information regarding foods, drugs, or cosmetics ~~as is necessary to protect against danger to public health or fraud upon the consumer, but such information regarding any brand of food, drug, or cosmetic gained under section 302, paragraph (i), or section 402, paragraph (c), shall not be so disseminated except~~ in cases involving imminent danger to health or gross deception of the consumer: ~~*Provided*, That nothing~~ *Nothing* in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of ~~his~~ *the* Department.

SEPARABILITY CLAUSE

SEC. 716. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 717. (a) This Act shall take effect twelve months after the date of approval. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this paragraph, is hereby repealed effective upon such date: *Provided*, That the provisions of sections 701 and 703 shall become effective on the approval of this Act, and thereafter, the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of subdivision (2) of paragraph (i) of section 302 for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by sections 303, 701, and 703: *Provided further*, That the Act of March 4, 1923 (U. S. C., title 21, sec. 6; 42 Stat. 1500 ch. 268), defining butter and providing a standard therefor, and the Act of July 24, 1919 (U. S. C., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form, shall remain in force and effect and be applicable to the provisions of this Act: *And provided further*, That amendment to the Food and Drugs Act, section 10A, approved June 22, 1934, shall remain in force and effect and be applicable to the provisions of this Act.

(b) The provisions of this Act shall not be held to modify or repeal any of the existing laws of the United States except as provided by paragraph (a) of this section.

Amend the title so as to read: "An Act to prevent the adulteration, misbranding, and false advertising of food, drugs, and cosmetics in interstate, foreign, and other commerce subject to the juridsiction of the United States, for the purposes of safeguarding the public health and preventing deceit upon the purchasing public."

This subcommittee has been appointed by the Commerce Committee of the Senate for the purpose of holding hearings on Senate bill 5.

The Chair would like to announce at the outset that hearings were held on a very similar bill to this bill for more than 4 weeks in the last Congress, and while it is the desire of the committee to give full and adequate hearings, it certainly is not the intention of the committee to permit the hearings to be unnecessarily dragged out as was done a year ago, and the Chair would like particularly to suggest that as little as possible be duplication of the same viewpoint before the committee.

The record will be kept open for a sufficient length of time to permit anyone who desires to submit supplementary briefs to do so, which will serve the same purpose so far as consideration of the full committee is concerned.

The Chair would also like to suggest at the outset that, in view of the very extensive hearings given on this bill in the last Congress, so far as the committee is concerned we would like particularly to have light on the position of the various parties desiring to be heard as to the changes in this bill from the bill of a year ago, rather than a repetition of the same agruments which were made at the hearings a year ago, which are still available to this committee.

I am going to undertake to operate this morning without establishing a definite time limit, but the committee desires all witnesses, in view of the large number of applications that we have had for opportunity to appear—that all witnesses be as brief as may be, and we would particularly like that no witness exceed perhaps 20 minutes. If it is possible to do that, the committee is not putting at this time any actual limitation upon the time.

The committee will first hear Mr. Dunn.

Mr. DUNN. May I ask the privilege of being heard later in the day?

Senator CLARK. The committee will hear Mr. Bristol. And the committee will say that it is going to be the desire of the committee to have witnesses testify as they are suggested, because if we undertake to permit witnesses to take their own places on the program we will get into inextricable confusion.

Mr. SETH RICHARDSON. May I ask the chairman of the special committee for permission, in behalf of the soap association, to file a memorandum?

Senator CLARK. We will be glad to have you do so. Any other parties who desire to file statements, or memoranda, or briefs with the committee rather than to testify orally may do so.

STATEMENT FILED BY SETH RICHARDSON, ATTORNEY FOR ASSOCIATION OF AMERICAN SOAP AND GLYCERINE PRODUCERS, INC., NEW YORK, N. Y.

Soap is a household necessity; not a drug or cosmetic.

Senate 5, Senator Copeland's bill to regulate foods, drugs, and cosmetics does not aim to place soap in any of those classifications. Commonsense definition and usage do not normally include soap among drugs or among cosmetics.

Unless the exclusion of soap from these categories is specifically provided, however, one of those most important items of everyday household use may be subjected to onerous imposts and confusions. The widest, most unrestricted use of soap is basic to public health, personal cleanliness, and civilized living. It is in the most fundamental sense a general necessity. Public interest therefore dictates that it be safeguarded against erroneous classification and technical confusions.

Unintentionally this bill may provide a technical precedent that will be misused to tax soap as a luxury or semi-luxury; to misrepresent it as a drug or a cosmetic and thereby discourage its free use; and to undermine the educational efforts of parents, school educators, and public-hygiene leaders for greater soap-and-water cleanliness.

Every menace to soap is self-evidently a menace to public health and decency. Whatever discourages the extensive and habitual use of soap in the home, office, factory, and school is a blow to the American standard of living. Even the minimum budget of the poorest American homes, including those on public or private relief, includes soap. The interests of soap must consequently not be allowed to suffer from oversight or default.

EXCLUDING SOAP FROM THE BILL

The purpose of the Copeland bill (Senate 5) is stated in the bill as follows: "To prevent the adulteration, misbranding, and false advertising of food, drugs, and cosmetics * * * for the purposes of safeguarding the public health and preventing deceit upon the purchasing public." With this purpose every reasonable person must agree. We are in hearty accord with it.

However, according to the definitions of the bill, soap would be among the products governed by its provisions if enacted in its present form (Committee Print No. 3). It is our earnest belief that the public interest does not require this and that the language of the bill needs clarification to prevent this unfortunate result. Soap is not a food, nor a drug, nor a cosmetic, and should be excluded from the definitions of the bill.

EXCLUDING SOAP FROM THE DEFINITION OF "DRUG"

We concede that those soaps which are represented for the treatment of disease may need to be covered by the drug sections of the bill. Such products are in fact so covered by the existing Food and Drugs Act. To this we have no objection. However, to make clear that section 201, subsection (b) of the bill, defining the term "drug", does not include soaps which through detergency aid in preventing disease and maintaining good health, we request (1) that soap be specifically excluded from the definition of "drug" by inserting in the subsection referred to, after the word "includes", on page 2, line 7 (of Committee Print No.

3) the words "except soaps not represented for the treatment of disease" or (2) that if it be desired as a matter of policy to avoid opening the door to proposals for other exceptions, that the same object be accomplished by a committee on commerce report to accompany the bill upon its submission to the Senate, stating clearly that the term "drug" does not include soaps except those that are represented for the treatment of disease.

While, as an industry, we would prefer to see this exception stated in the bill itself, we defer to the judgment of your committee as to which is the better means of accomplishing the above-stated objective. The objective itself is one with which we believe the committee will agree.

EXCLUDING SOAP FROM THE DEFINITION OF "COSMETIC"

We turn now to the definition of the term "cosmetic." The present definition in the bill might be interpreted to include soap.

Soap, however, is not a cosmetic. Funk & Wagnalls Dictionary defines a cosmetic as "a powder, paste, or other compound applied to the skin in order to improve its appearance". The same dictionary defines soap as "any compound formed by the union of a fatty acid with a base * * * used as a detergent." The nature of soap differs entirely from that of a cosmetic. It does not need the regulations proposed for cosmetics. Soap cannot be adulterated or misbranded in the sense meant in the bill, and the entire history of universal public use of soap demonstrates that it is not injurious but is, on the contrary, an everyday necessity in every home in America.

Therefore, to exclude soap from the definition of "cosmetic" given in section 201, subsection (c) of the bill, we ask that there be inserted in this subsection, on page 2, line 17 (Committee Print No. 3), after the word "preparations" the words "except soap", so that the amended definition will read:

"(c) The term 'cosmetic' includes all substances and preparations, except soap, intended for cleansing or altering the appearance of, or promoting the attractiveness of, the person."

REASONS FOR EXCLUDING SOAP FROM THE BILL

It seems unnecessary to argue at length in favor of the above requests. To include soap with drugs or cosmetics implies a danger in use and a consequent possibility of menace to public health, which danger and menace is directly contrary to the nature and benefits of soap itself.

Furthermore, soap-and-water cleanliness, recognized as the foundation of everyday hygiene and public health, is constantly being assailed by self-seeking faddists. On the basis of false claims, they try to persuade the public to use all sorts of substitutes for soap: various muds and chemicals instead of common-sense soap and water. They want dirt covered up and its odors disguised, instead of having it washed away in the normal fashion.

Anything that identifies soap as a "drug" or "cosmetic" plays right into the hands of such faddists. It gives them another weapon in attacking soap, advancing false claims, and exploiting the public. For the protection of the American consumer, therefore, soap must not be thrown indiscriminately into the same class with cosmetics and drugs. Its distinct and obvious character as a common household necessity must be safeguarded.

Additional reasons for excluding soap from the bill are given in a supplementary statement attached hereto. Such reasons are sane, potent, and conclusively in favor of the request we make. We especially direct attention to the paragraphs on taxing cleanliness and health, for this points to the extremely heavy burden of regulation, and especially of taxation, which the precedent of the Copeland bill, if unchanged, would directly lead to in many, if not all, of the 48 States.

This danger cannot be overestimated. It is already upon us. Among States in which up to this date (Mar. 2, 1935) proposals have been made to regulate or tax soap (up to 10 percent) under definitions primarily intended for cosmetics or drugs, and which definitions largely follow the precedent established in the discussion of the Copeland bills of last session and this, are California, Connecticut, Kentucky, Maine, Missouri, New York, North Dakota, Ohio, and Utah. Such addition of unnecessary regulations and taxation upon an everyday household necessity is unwarranted. One result would necessarily be an increase in the costs of soap itself, together with other deterrents against its use. Such a result would reduce the public health protection afforded by soap, lead to lower standards of living, and be directly contrary to the very purposes of the Copeland bill itself.

The requests thus submitted for the exclusion of soap from the Copeland bill are made by the American soap industry's national association on behalf of all companies in the industry. Our directors, listed below, have been instructed in this matter by a general national meeting of the industry, which was attended by more than 50 companies making more than 95 percent of all the soap made in the United States. The action of the meeting was unanimous; and on behalf of out entire industry we pray for your favorable consideration of the requests we make.

Association of American Soap & Glycerine Producers, Inc., by H. D. Banta, Iowa Soap Co., Burlington, Iowa; N. R. Clark, Swift & Co., Chicago; S. B. Colgate, Colgate-Palmolive-Peet Co., Jersey City, N. J.; F. A. Countway, Lever Bros. Co., Cambridge, Mass.; N. S. Dahl, John T. Stanley Co., New York; R. R. Deupree, Procter & Gamble Co., Cincinnati; G. A. Eastwood, Armour & Co., Chicago; S. S. Fels, Fels & Co., Philadelphia; I. Katz, J. Eavenson & Sons, Inc., Camden, N. J.; F. H. Merrill, Los Angeles Soap Co., Los Angeles; W. C. Wollen, Olive Oil Soap Co., Paterson, N. J.; C. F. Young, Davies, Young Soap Co., Dayton, Ohio; Roscoe C. Edlunds, association manager, and Richardson, Davies, Beebe, Busick & Richardson, counsel.

SUPPLEMENTARY STATEMENT OF REASONS FOR EXCLUDING SOAP FROM LEGISLATION AIMED TO REGULATE DRUGS AND COSMETICS

In an article published February 1, 1935, Dr. Royal S. Copeland said: "Children should be taught the importance of neatness and cleanliness at an early age. This habit once established will protect against disease and infection. The children should be taught that the hands must always be washed before touching food, and always be kept reasonably free of grime and dust."

The enthusiastic endorsement of soap and water cleanliness for children and adults is universal among medical exports and health authorities. An almost unlimited amount of additional evidence could be produced to support this statement. The list of these authorities includes innumerable Federal and State health officers and also such noted authorities as: Dr. Harry Beckman, Dr. F. A. Diasio, Dr. Morris Fishbein, Dr. Iago Galdston, Dr. Sigmund S. Greenbaum, Dr. Oscar Levin, Dr. William E. Pusey, Dr. Milton J. Rosenau, Dr. John E. Walker, and many others.

No physician, no mother, would deny that a child should be taught the freest possible use of soap at the earliest possible age. But no physician or mother would similarly endorse the freest possible use by young children of drugs or cosmetics.

Plainly, in any normal use of the term, soap is not a "drug" and not a "cosmetic".

Millions of parents, thousands of health workers, face the necessity, day after day, of underlining the important distinction between soap on the one hand and "drugs" or "cosmetics" on the other. That distinction is significant in terms of personal hygiene, health habits, and civilized living.

Reduced to essentials, it is the distinction between a product that is commonplace, completely accepted, always safe, and whose use is a highly desirable habit; and other products which must be carefully considered, regulated, used with discretion, and sometimes prescribed.

We urge that it behooves the present bill to take this obvious distinction into consideration. Any confusion must in the long run defeat those parents and health workers in the efforts to extend cleanliness habits among children and adults alike. It will provide a toehold for misrepresentation.

What we request is in effect a recognition of the practical, common-sense definition of soap as against legalistic, hair-splitting interpretations. Such misinterpretations are not intended by the framers of the bill, who must, therefore, concur in our suggested clarification. In dealing with an item so basic to life, health, and happiness, the need for clarity should not be overlooked.

Already the loose classification of soap among cosmetics (placing it erroneously in the same category with some luxuries and semi-luxuries) has led to difficulties in the application of trade codes, unjustified taxation, and other difficulties harmful alike to the general consumer and to the soap trade.

SOAP NOT A DRUG

Medical literature is replete with evidence that soap and water is a factor in maintaining bodily health, as potent, and almost as natural, as fresh air or sunlight.

Public acceptance of this fact is so universal that it requires but the briefest upport. To quote Dr. Copeland again in a recent article: "A good soap removes he surface films that contain dirt and undesirable germs. It promotes cleanliness, naking certain protection against germs and disease."

Such statements do not mean that because soap and water powerfully assist in the prevention of disease, that therefore soap can properly be classified as a drug. The action of soap is primarily to wash away dirt, and with the dirt go the germs harbored therein. This is made clear in another quotation from Dr. Copeland: "To guard against this danger (transmission of disease germs by hands) it is not necessary to resort to the use of antiseptics and disinfectants. In fact, the too liberal use of some antiseptics may lead to an irritation of the skin. But liberal amounts of soap and water insure cleanliness without disturbance of the skin surface."

The assumption that anything which promotes health is therefore a drug, is a dangerous fallacy. Soap is the oldest, the most widely used, and most potent necessity in preventing disease. That does not make it a drug—any more than water and sunlight, fresh air and good food, exercise and clean towels, all of which promote health and prevent disease, are drugs.

However, in Senate bill 5 (Committee Print No. 3) the term "drug" is defined in part as including "(2) *all substances* * * * intended for use in the * * * prevention of disease." It may readily be seen that this language, if uncorrected, might readily be interpreted to include all soaps and not merely those which are represented for the treatment of disease. Herein lies the danger of the language as it reads at present.

It is recognized that the proposed definition of "drug" follows closely the Food and Drugs Act of 1906. It is also recognized that the Department of Agriculture has taken the common sense view that soaps are not included, except those represented for the treatment of disease. But since the prevention of disease through cleanliness is an important purpose to which soap and water are applied, literal interpretation of the proposed language (as opposed to the common understanding) might attempt to classify all soaps as drugs on this ground. No such purpose is intended, but the language should be clarified beyond any possibility of misinterpretation. This clarification can be achieved in either of the two ways mentioned on page 2 of the opening statement.

SOAP NOT A COSMETIC

That soap is not, in any normal sense of the word, a cosmetic, is evident.

A short time ago a survey was made to learn what products women themselves considered to be cosmetics. The results of this survey are of great importance.

Question: "What products do you consider are cosmetics?"

Answers (entirely by women):

Products mentioned:	*Percent of replies*
Powder	99. 1
Rouge	83. 6
Lipstick	71. 0
Creams	58. 0
Astringents	9. 1
Lotions	8. 2
Mascara	5. 5
Cold cream	5. 5
Eyebrow pencil	3. 6
Eye shadow	2. 7
Vanishing cream	2. 7
Cleansing cream	. 9
Toilet water	. 9
Anything to beautify	. 9
Anything you apply to your face	. 9

Not one woman of whom the above question was asked, mentioned soap as a cosmetic. Experience assures us that this survey could be multiplied many times with sensibly the same verdict.

Thus it is evident that women who use cosmetics do not consider that the soap they use is a cosmetic. From this, one can appreciate the fallacy of classing soap,

which provides the entire population with its most important means of securing personal cleanliness, with luxury cosmetic products that are used only by a limited proportion.

The use of soap by the public is so common that simple illustrations will serve to make our point:

When the schoolboy is sent home from school to be washed, does anyone consider he is being primped with a cosmetic?

When a baby is washed with soap and water, is it done for beautification as a cosmetic, or to keep the baby clean?

When workmen, farmers, mechanics, or artisans wash their hands and faces after their labors, is it to be understood that they are engaged in using a cosmetic?

Home and school education is teaching 25,000,000 young children to wash their hands and bathe their bodies. This instruction does not teach children the use of cosmetics.

The harmless nature of soap cannot be too strongly stressed. It can almost be said categorically that no one was ever harmed by the use of soap. The care and judgment with which drugs must be used or cosmetics applied, when contrasted with the common use of soap and water, further makes the distinction clear.

Can there be any question that soap is not a cosmetic and that it should not be so defined in the bill?

TAXING CLEANLINESS AND HEALTH

In legislation, the action of Federal and State authorities is frequently complementary. What Congress does affords precedent for the States. Under these circumstances, if soap is classified by Congress under drugs and cosmetics, such classification immediately opens the door to regulations by 48 State jurisdictions.

The danger is enhanced by the increasing need of States for revenue. What starts with regulation, quickly becomes taxation. In the case of taxation on cosmetics, generally regarded as luxuries, the taxes are exceedingly heavy. Ten percent is common, which when applied to soap under a possible Federal precedent that it too is a cosmetic, is oppressively burdensome.

That the danger thus stated is far from imaginary is shown by situations that have already arisen in the nine States named in our opening statement. On the basis largely of the widespread discussion which followed the Copeland bill of the last Congress, together with the attention which the current bill has received, these States have advanced regulatory and tax proposals, which, if passed, would be extreme.

These State bills, as already indicated, propose excise or stamp taxes as high as 10 percent upon the sales price. However proper such proposals may be with reference to luxuries or semi-luxuries, no one will argue that they are proper when applied to everyday articles of necessity. Upon soap, used daily in every American home, taxes of this magnitude are oppressive. They fall heaviest upon those least able to bear them. Such proposals, even when they spring from purposes originally intended for public good, are a distortion of those purposes and are contrary to every dictate of public policy.

A tax on cleanliness is a tax on health. It destroys instead of building up public welfare. If such result should flow—as we now have tangible evidence that it will—from a Federal bill such as your committee has before it, it would be a travesty upon the very purposes the legislation aims to serve.

The importance of this aspect of the definitions of drug and cosmetic in the measure before you, cannot be overstated. In our judgment, it is imperative from the viewpoint of public policy, that soap be clearly excluded from such definitions. If this is not done, it will lead, in the States, to untold complications and tax expense. It will increase the cost of one of the best agents of health the poor man has. The result would be that instead of protecting and assisting the health of the people, which is a primary object of the Copeland bill, precisely the opposite would occur.

To us this seems one of the most potent reasons for the changes in definitions of drug and cosmetic which we ask you to make. We have made these suggestions in order that the bill shall truly become an instrument for the purposes intended and shall not unwittingly defeat the ends for which it is designed. This latter it will certainly do if it lends precedent to State legislation for the inclusion of soap under drugs and cosmetics. With all the earnestness at our command, we urge that you do not permit this to happen and that on the contrary you make the

changes which we ask, and which in our judgment are vitally necessary to protect public interest.

BOARD OF DIRECTORS ASSOCIATION OF AMERICAN SOAP AND GLYCERINE PRODUCERS, INC.,
ROSCOE C. EDLUND, *Manager*,
SETH RICHARDSON.

Mr. DUNN. Mr. Chairman, I will be very glad to testify now.

Senator CLARK. Very well; you may do so.

STATEMENT OF CHARLES WESLEY DUNN, NEW YORK, CITY N. Y,

Mr. DUNN. Mr. Chairman and members of the committee: I have the privilege of representing at this hearing the Associated Grocery Manufacturers of America, Inc., which includes outstanding and representative food manufacturers of the country. It is in effect the National Association of Food Manufacturers, and to indicate to you the extent of the business represented, I may state that it approximates some four billion dollars per year.

I also have the privilege of representing at this hearing the American Pharmaceutical Manufacturers Association, which includes pharmaceutical manufacturers who serve the medical profession.

I further represent the National Association of Dog Food Manufacturers, which is a very large organization of manufacturers of animal food, and I also represent myself.

It gives me a great deal of pleasure, Mr. Chairman and gentlemen of the committee, to endorse this bill, S. 5, in behalf of the industries I represent, with the amendments written in the bill that I have submitted to Senator Copeland. We feel that with these amendments——

Senator CLARK (interrupting). Are those amendments included in the present draft of the bill or are they additional amendments which have been proposed?

Mr. DUNN. They are additional amendments which have been proposed and submitted to Senator Copeland, and he has them in his possession, and I assume they will be made a part of the record of this hearing.

Senator COPELAND. I think it might be well, Mr. Dunn, for you to specify what those amendments are.

Senator CLARK. If you could briefly summarize them, I think it will be in the interests of all concerned.

Mr. DUNN. Very well; I shall do so. If I happen to omit some of these amendments, Senator Copeland, I wish you would correct me.

Senator CLARK. Mr. Dunn, I am advised by those in charge of the amplifying apparatus that it is so arranged that if you would be seated, you can be heard better than if you stand.

Mr. DUNN. Yes, sir; thank you.

Now Mr. Chairman, I am going to read into the record, the amendments I have submitted to Senator Copeland in behalf of the industries I represent, and I will add a comment upon each of them as I read them. On page 41 of the Senate bill 5, third print, I have recommended, and Mr. Campbell and Senator Copeland have accepted, the following amendment of the first sentence of section 710. The revised section will read:

Before reporting any violation of this act to any United States attorney for institution of criminal proceedings thereunder, the Secretary shall, in accordance with regulations prescribed by him, afford due notice and opportunity to interested persons (a) for hearing upon the question of such violation; and (b) for hearing to review his decision to make such report upon cause shown satisfactory to the Secretary.

The purpose and effect of this amendment is that when the Secretary decides to institute a criminal prosecution against a manufacturer, he shall notify the manufacturer of his intention to so prosecute him, and the manufacturer will thereupon have an opportunity for a review of that decision upon cause shown satisfactory to the Secretary. This will give the industry an opportunity to correct any unwarranted decision for criminal prosecution.

Senator CLARK. That would simply be in the nature of a motion for rehearing before the Secretary?

Mr. DUNN. Yes, sir. But at the present time, under the present law, the manufacturer never knows of a criminal prosecution until it is actually instituted in court.

The next amendment is on page 15, line 13. This is the paragraph which sets up a standard of validity of therapeutic representations for drugs.

I have recommended that the words "in every particular of" in line 13 and the word "it" in the same line be stricken out for the reason that this language is unnecessary, and the section has the same strength without it, therefore it is not justified as an addition.

I have further recommended that in line 14, the words "and reliable" be inserted before the word "medical" so that a therapeutic representation for a drug would be deemed to be false unless it is supported either by demonstrable scientific facts, or substantial and reliable medical opinion. The addition of the words "and reliable" is essential from the standpoint of protecting the consuming public, because the word "substantial" connotes a numerical opinion, and a numerical medical opinion may not be an opinion upon which the public can safely rely, therefore, with the addition of the words "and reliable" the public will be assured that any therapeutic representation to be used legally under the act must be supported by a substantial and a reliable opinion or by demonstrable scientific facts.

That amendment has been approved by Mr. Campbell and has been accepted by Senator Copeland.

On page 24, lines 3 and 4, we have here the same situation with respect to false advertising and the same amendments have been suggested and for the same reasons.

On page 16, line 25, after the word "ingredient", put a colon and add this proviso:

Provided, That, to the extent that compliance with the requirements of subdivision (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

The reason for that addition is this. This paragraph requires a nonofficial drug which is fabricated from two or more ingredients, to declare the name of each active ingredient upon the label, and the addition of this proviso is to empower the Secretary to make any exemptions to that requirement where the requirement is impracticable. The same provision is in the bill with respect to food, and the declaration of the ingredients on the label of food, and we are merely repeating the proviso as to drugs.

This addition has been approved by Mr. Campbell and has been accepted by Senator Copeland.

On page 26, line 22, insert a comma——

Senator CLARK (interrupting). All of those typographical errors have been corrected in the bill.

Mr. DUNN. Then I will not refer to the typographical errors. I was about to say there should be a comma after the word "condemnation".

On page 25, line 20, take out the words "complaint of" and substitute therefor the words "petition by", for the reason that on page 26 the reference is to the petitioner in each instance.

On page 31, lines 9, and 12, make the word "or" read "and/or". In line 17, put a period after the word "Act", and strike out the balance of that sentence.

You will note that in this last sentence there is a reference to the antitrust law. That reference has no place in the Food and Drug Act. The antitrust law applies in any event.

The next amendment is on page 32, line 2. This is an amendment of section 705 which deals with examinations and investigations under the act, and we suggest the following new sentence in line 2:

If a sample of a food, drug, or cosmetic is taken to determine whether it is adulterated, then a representative part of such sample shall be promptly delivered to the person interested and upon application the Secretary shall inform such person of the method of analysis administratively used and of any tolerance administratively recognized with respect of such article under this act.

Senator COPELAND. In my copy I placed "upon application" after the word "and". Is that just as well?

Mr. DUNN. Yes, that is just as well.

The effect of that amendment, Mr. Chairman, is this, to require that where a sample is taken for the purpose of determining whether the product is adulterated, before a criminal prosecution, that the manufacturer shall receive a representative part of that sample. It is now provided in the bill that in a seizure proceeding, the claimant shall have the right to receive a representative sample of the product seized. It is much more important, where a criminal proceeding is instituted, that the manufacturer shall have a representative part of the sample which is taken by the Government for the purpose of determining whether it is adulterated, because in the absence of the receipt of that representative part of the sample for check analysis, the manufacturer is often put in the position where he is powerless to meet the charge of violation. He should be put in precisely the same position as the Government with respect to the sample taken, have the same opportunity to analyze it, and the same opportunity to present his evidence at the hearing.

The other part of the amendment is to require the Government upon application by the manufacturer to inform him of the official method of analysis and of any official tolerances which are recognized by the Government in the administration of the act with respect to that particular sample.

As you know, Mr. Chairman, it is very frequently the case that the question of the adulteration of a food or drug depends entirely upon the method of analysis used in its examination. Therefore, the manufacturer, in order to meet the charge of the Government, must be in a position to analyze the sample by the same method which the Government used, and he should be informed of that method by the Government at the time. It is a perfectly fair and sound amendment.

The next amendment is on page 42, line 9. This is the section which empowers the Government to make seizures, and the first sentence, which is the sentence amended as I shall indicate, contains that provision empowering the Government to make the seizure. The suggested amendment is to add a comma after the word "found" in line 9 and then to include the following clause:

if it appears to the court that such proceeding is necessary to effectuate the purposes of this act.

The point of that amendment is this: That as a rule now, the court makes the seizure upon application by the Government, and the effect of this amendment is to require the court to examine the papers, the application for the seizure, and to determine whether the seizure is necessary to accomplish the purposes of this act.

Seizure is a very drastic proceeding and it ought to be instituted where the purposes of the act require it, and through this amendment the burden is left upon the court to determine the question whether the seizure should be made in order to accomplish the purposes of the act.

The next amendment is of the same section on page 45, line 14. We are here dealing with the matter of multiple seizures and the suggested amendment is the addition of a new sentence in line 14 reading as follows:

In cases of multiple seizures of an article of food, drug, or cosmetic under the provisions of this section at least one such seizure shall be made in the jurisdiction of the United States District Court for the district where the person whose name appears upon the label of such article has his principal place of business, if the article is available for such seizure therein; if such article is not so available, then at least one such seizure shall be made in the jurisdiction of the United States District Court for the district nearest to such place of business wherein the article is available for such seizure.

Senator CLARK. This is to be, as I understand, inserted at the end of line 14?

Mr. DUNN. Yes, sir. The effect of that amendment, Mr. Chairman, is this. It leaves the Government with their power for multiple seizure subject to the present provisions of the section, but it provides that where the Government does make a multiple seizure, it shall at the same time make a seizure in the district where the manufacturer concerned has his principal place of business if the article is available for seizure there, or in the nearest district if it is not available there, in order that the manufacturer may have the trial of the consolidated case which this section provides for, at a place that is convenient for trial. If the manufacturer, for example, is located in New York City and the seizures are made out West, then he is required to go to the West for the trial. Under this provision, the trial might be held in New York City.

Senator COPELAND. Will you also comment on lines 8 and 9 on the same page?

Mr. DUNN. Yes. In lines 8 and 9 we have also recommended that the language "which is nearest to the place of business of such claimant" be eliminated for this reason: This sentence in section 711, the seizure section, provides in effect for the consolidated trial of multiple seizures where the issue is the same in all of these various

seizures, and as the sentence is now drawn, the consolidated trial must be held in the district that is nearest to the place of business of such complainant. It may be that there is some valid reason why the trial should be held in another district, so that by striking out this restrictive language you leave the situation where the claimant can apply for the trial of the cause in any of the districts where the multiple seizure was made.

Senator COPELAND. It gives him latitude to use the district where he shall have the multiple trial set up.

Mr. DUNN. All subject to the approval of the court, so that the public is fully protected.

The next amendment, Mr. Chairman, that we suggest is on page 33. This amendment deals with section 707, which relates to factory inspection. Section 707 contains two paragraphs, paragraph (a) and paragraph (b). Paragraph (a) empowers the Secretary to make a factory inspection for the purposes of this act. We are entirely in accord with the principle of paragraph (a). There should be the power of factory inspection for purposes of this act, but the difficulty is in paragraph (b), which provides the penalty for a refusal to permit this inspection. As the paragraph (b) is now drawn, if a manufacturer refuses to permit this inspection, then the court is authorized to issue an order preventing all interstate commerce by him. This is the most drastic penalty in the whole act.

Let us assume, for example, that some inspector comes into the plant of a reputable manufacturer, and for any reason has an obnoxious presence or makes an unwarranted request. That is not beyond the realm of probability—abuse, in other words, of his administrative power, and the manufacturer in his righteous indignation just simply says, "No."

Under this provision (b) here, you can close that whole business up. We are agreed to the principle that where the factory inspection is improperly refused, there ought to be an adequate remedy against the refusal, so we suggest that paragraph (b) be rewritten to read as follows:

> The several district courts of the United States are hereby vested with jurisdiction (1) to order the disclosure of a private formula or a secret process in pursuance of an inspection made under this section, if and to the extent such disclosure is necessary for the purposes of this act, and in such case only, and (2) to restrain by injunction, temporary or permanent, any refusal to permit the entry and/or inspection authorized by this section. Violation of any such order or injunction may be summarily tried and punished by the court as a contempt. Such contempt proceedings may be instituted by order of the court or by the filing of an information by the United States attorney.

That gives the court complete power to enjoin a refusal of a proper factory inspection, which is what is desired here, but the power of the court, you see, is limited to the offense, which is the refusal of the factory inspection, and it does not go beyond that and authorize the court to close down the whole business of the manufacturer because his shipment of foods and drugs and cosmetics may be entirely legal, they may be properly labeled, and they may be wholesome in every respect.

Moreover, this paragraph has the additional value of giving the power to the court to protect private formulas or secret processes up to the point that their disclosure is not required for the purposes of this act. If their disclosure is required for the purposes of this act through a factory inspection, then the court should have the power to compel it.

The only objection made to this amendment which I have offered is the one that it may be unconstitutional.

Now, Mr. Chairman, my answer to that is this: The question whether section 707 authorizing a factory inspection is constitutional or not depends upon the provisions of paragraph (a) which authorizes the factory inspection. If paragraph (a) is valid in authorizing the factory inspection, then you may have any valid penalty or remedy against the refusal to permit the authorized inspection. So that as I say, if paragraph (a) is valid, it makes no difference what penalty you have in paragraph (b). If paragraph (a) is invalid, then any penalty you have in paragraph (b) falls along with paragraph (a). I believe that paragraph (a) should be rewritten to secure more effectually its constitutionality.

I have grave doubts about its validity at the present time. However, this section can be rewritten to more thoroughly strengthen the constitutionality of paragraph (a), and there is a reasonable ground to believe that if the paragraph is then so rewritten that the court may sustain its validity.

In any event, the remedy for a refusal to permit that factory inspection is clearly the one we have submitted.

Senator COPELAND. Your idea is that it ought to be tied up more closely with the commerce clause?

Mr. DUNN. Yes; in other words, the way that paragraph (a) is now written, its standard is the public welfare, the public health, and the public interest, whereas the constitutional standard is the commerce clause, and, therefore, if you are going to write this section in the strongest constitutional way, you should directly relate it to the commerce clause as closely as you can, subject to all of the difficulties of the situation here presented, namely, that you are dealing with a factory inspection inside of a state. I hope this section can be drawn to make it proof against constitutional objection.

Senator COPELAND. You have agreed to supply language that you think would effect that in paragraph (a).

Mr. DUNN. Yes, sir. I have submitted other amendments to Senator Copeland and they have been approved by the Government. For example there is one on page 53 amending the title of the bill to expressly provide in the title that its purposes are to safeguard the public health and to prevent deceit upon the purchasing public. That is a very important amendment for the reason that the definitive provisions of the act are all general, and the court always refers to the title as the standard for construing these general definitive provisions. Therefore, you should state in the act what its purposes are as a basis for construction of these general provisions.

I am not going to, at this time, mention the other amendments which I have made, because I have no record of them here. But before concluding my testimony, Mr. Chairman, I want to say this: That the industries I represent are opposed unqualifiedly to the transfer of the enforcement of false advertising provisions of this bill to the Federal Trade Commission which has been proposed. We are opposed to that transfer because we believe it is directly contrary to the public interest, and the reasons for our belief may be perhaps summarized as follows:

In the first place, there is no logical or sound reason, from the public standpoint, why the Department of Agriculture which is now empowered to enforce the law with respect to the label and the product should not be given the same power with respect of the advertisement, because the questions of administration are all interrelated. When you deal with the advertisement, you are dealing with questions that come up in determining the adulteration of the product and the truth or falsity of its label. You have a single and unified administrative problem.

In the second place, the Federal Trade Commission has no scientific organization whatever. It is not equipped or positioned to deal with scientific questions. Its organization consists of economists and lawyers and laymen, and when it deals with these scientific questions, it has to refer principally to the Department of Agriculture in any event. Why should you have a secondary enforcement through an agency, a Government agency, that is neither equipped nor positioned to deal with these matters of administration that are purely scientific in character?

In the third place, we believe that a false-advertising law of this sort should have a criminal penalty, that it can only be best and most effectively enforced if the Government has the alternative remedy of injunction or criminal prosecution. If you transfer the enforcement of these false advertising provisions to the Federal Trade Commission, you have the situation left where all that the false advertiser has to fear is a cease and desist order. That is not enough in this situation, as we view it, and you are not going to have anything like the measure of compliance or the measure of efficient enforcement if you transfer this enforcement to the Federal Trade Commission that you have with the Department of Agriculture.

There is another reason. In the Raladam case, the United States Supreme Court held in effect that the Federal Trade Commission has no jurisdiction over a false advertisement for the purpose of preventing it, unless it establishes not only that the advertisement is false but that it is unfair to a competitor.

If that rule prevails in the enforcement of this act, you are injecting a factor of a condition precedent to the application of the false advertising provision which is wholly foreign to this food and drug law. It makes no difference whether the advertisement is unfair to a competitor. The decisive question is whether it is false, and if it is false, then it ought to be prohibited.

Senator COPELAND. And harmful to the consumer.

Mr. DUNN. Yes; and harmful to the consumer.

It may be argued and argued successfully that the amendment transferring the power of enforcement to the Federal Trade Commission of these provisions could be so drawn as to eliminate the rule in the Raladam case. That is so; that is entirely so, although it has not been done in the Mead bill, but even assuming that we could draw the amendment so as to eliminate this restrictive ruling, you are still left with the broad question whether it is in the public interest to transfer the enforcement of the false advertising provisions to the Federal Trade Commission.

It will be a rather strange situation in which you are left, to find that the Government is empowered to proceed by criminal proceeding with respect of adulteration and labeling but is only empowered to proceed by a civil proceeding with respect to the false advertising, which is relatively the greater offense in a practical sense. There is no reason whatever in public policy in our judgment why this transfer should be made.

The only reason for the proposal is to, somehow or other, soften off this enforcement of the false-advertising provisions of the law.

I have had considerable experience with the enforcement of the Federal Trade Commission Act. I carried the Beechnut case to the United States Supreme Court, and I think it was the first case to come out under that act, and my observation is that there is no comparison in efficiency of enforcement from the standpoint of celerity and decisiveness of action between the enforcement of the Food and Drug Act as it is now carried on, and the enforcement of the Federal Trade Commission Act. It is much quicker through the Department of Agriculture, and it is much more effective as an administrative procedure.

I am not saying for a moment that the administration of the Federal Trade Commission has not been an effective thing. Of course it has. I am comparing the two processes of administration, that from the standpoint of public health, from the standpoint of protecting the consuming public in this country, and you have a more efficient and a more effective procedure through the Department of Agriculture than you have through the Federal Trade Commission, and to think of making the Federal Trade Commission the protector of the public health in the matter of false advertising with respect to food and drug administration when it has no scientific organization whatever and must depend upon the Department of Agriculture is just mistaken thinking and erroneous conception of administration.

It may be argued that the Federal Trade Commission has done a great deal to prevent false advertising under the present act. That is entirely true, but I will say to you that in my observation, dealing with the whole problem of food and drug advertising, it has been a relatively small thing. I want to leave my industries that I represent on record before this committee that we are opposed to any weakening or emasculation of this bill in that way.

Secondly, I want to, Mr. Chairman, say that we very sincerely hope that the committee will promptly report this bill as it has been amended and that this bill be speedily enacted by Congress. This is a fine bill, as it has been amended, and the public is going to gain immeasurably in protection as a result. You have here a revised bill which thoroughly and effectively prohibits false advertising of foods, drugs, and cosmetics, you have the control of cosmetics thoroughly taken care of, you have the act broadened to include all of these mechanical devices for therapeutic uses and all of these preparations and products which are sold to correct the function and structure of the body, such as obesity preparations which were not covered by the act, and you have the present adulteration and misbranding provisions very greatly strengthened.

I only need to refer to one thing, for example, and that is, as the amended bill is drawn and is before you, it deals with the question of sanitary production and prohibits a food, drug, or cosmetic from being sold which is produced under insanitary conditions which render this dangerous or injurious to the health of the public. That amendment alone would warrant this whole revision plan.

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And then, aside from the new provisions, aside from strengthening the present definitive provisions, you have the enforcement and administrative provisions very greatly enlarged and very greatly strengthened by the addition of the injunction proceeding, for example, by the addition of provisions for publicity, and so on.

So that the legitimate food and drug interests of this country must in conscience support the revised bill as amended, and the public interest will be greatly benefited by the speedy enactment of this bill.

Senator CLARK. Is Mr. Bristol present?

Mr. BRISTOL. Yes, Mr. Chairman.

STATEMENT OF LEE BRISTOL, OF BRISTOL-MYERS CO., NEW YORK

Mr. BRISTOL. Mr. Chairman and members of the committee, I promise you that I shall be very brief. I represent myself as an officer in a company in one of the affected industries. Our company operates in the drug and toilet-goods field. As vice president of that company, and active in the company, I am speaking not solely for myself but for the company, for our stockholders, who number 20,000, and for 600 employees.

Senator CLARK. What is the name of the company?

Mr. BRISTOL. The Bristol-Myers Co. And also for the 8 to 10 million customers, consumers, whom we have been serving and with whom we have kept the faith for nearly 40 years. Had we not kept the faith, probably 39 years ago would have marked the termination of our company.

In considering S. 5, it is rather an anomalous position that one is put in in taking exception to some of the provisions that have been made, for it would appear as though a person who classifies himself as being of the decent group is trying to protect and defend those for whom the law is definitely designed.

I want to go on record as saying two things: First, that our company—and to the extent that I might be representative of others who I hope constitute the decent section of the drug industry—would welcome a restriction as proposed to limit the action of the fakers, cheats, and fraudulent companies; that furthermore we do sincerely hope that legislation will be passed and that legislation will be passed at this session of Congress.

I have no desire to stand in defense of any groups that are not worthy of continuation of life in the industrial picture, but I want to point out two major points that to me appear important, and I speak not as a lawyer but as a manufacturer in the affected industry.

Supplementing that, I have two other points which I believe are proposed, of less specific importance but bearing upon the question. The first point to which I want to address myself is the matter of seizure. Those of us in the industry who appreciate the restrictions proposed for adulteration are very anxious, willing, and in full accord, that the process of law in the form of multiple seizure shall apply. There is no attempt on our part or desire on our part to curtail that right. However, we do believe that in matters of misbranding (except in cases where the public health is definitely endangered, where by court injunction adequate protective steps for the consumer should be

taken) that in those matters involving misbranding, single seizures should be provided for.

I am not speaking as a lawyer, and to that extent I am not asking any of you to accept my phraseology other than perhaps to state that I believe another bill that has been introduced does cover that point. I refer to the bill of Representative Mead, as introduced in the House of Representatives.

The second point that I believe is important, relates to the matter of regulations. Under the proposed bill, the department is empowered to anticipate unforeseen contingencies and to set up restrictions by the issuance of regulations that may have a very important bearing upon the operation of the affected industries. The wording of S. 5 provides that such provision shall also have the coordinated cooperation, shall we say, of a committee appointed of five men that have marked themselves with distinction in these fields of foods, drugs, or cosmetics.

In the case of drugs, however, that has a unique significance, because to qualify under the terms that the committee has set up, it would seem to me at least as though that indicated that the committee should be composed of five doctors. Where a matter of self-medication was involved, it would seem as though the committee was sufficiently prejudiced by the character of its nature to render it unqualified to fairly sit in judgment on regulations affecting such matters.

Senator COPELAND. Will you call specific attention to where that appears in the bill?

Mr. BRISTOL. I haven't it in front of me now, sir, but under the section entitled, I think, regulations, where the committee of five is appointed by the President without reference to their political affiliation, of those who have rendered distinguished service in the fields of food, drugs, or medicines. And that wherever the word "regulation" appears throughout the bill, the Secretary and the Department, by and with and in cooperation with them, shall determine the addition of restrictive regulations.

Senator COPELAND. Of course, the objection last year was that power was left arbitrarily in the hands of the Secretary.

Mr. BRISTOL. Right.

Senator COPELAND. And to avoid that here, we set up a board of review in the matter of the regulations.

Mr. BRISTOL. Right.

Senator COPELAND. And that the majority of that board must pass upon them.

Mr. BRISTOL. Yes.

Senator COPELAND. And we felt that we should change it this year to make sure when we selected these men, that they were men who were interested in these particular fields, and that they should not be physiologists or bacteriologists or something else, so that would seem to me to be covered.

Mr. BRISTOL. Was it your interpretation, Senator, that those five would or would not be medical men?

Senator COPELAND. Medical men.

Mr. BRISTOL. All I meant was that the general basis for having a board of medical men sitting in judgment on matters involving self-medication automatically set up a type of control that was unfair.

Senator COPELAND. Let us refer to the self-medication if the chairman will permit. Where is that list of diseases?

Mr. BRISTOL. I appreciate, Senator, that that list has been very definitely curtailed from last year.

Senator COPELAND. I want to call your attention to another matter. On page 24. Personally, I never wanted this list in as far as I am concerned, but when we discussed the matter, we took those things which are obviously——

Mr. BRISTOL (interrupting). Incurables.

Senator COPELAND (continuing). Cancer, tuberculosis, venereal diseases, heart and vascular diseases. So far as I am concerned, I would be perfectly willing, for myself, to cut out of this bill any reference to additions to that list. Do you see what I mean?

Mr. BRISTOL. Yes.

Senator COPELAND. If it should develop that some other disease that we do not know much about now should come into prominence, it would be very easy to amend the bill and make that addition. So I think that would answer your criticism.

Mr. BRISTOL. One other factor—two others that I just want to speak to briefly.

We have operating in the drug field the problem of working under a restriction of legislation in 40 different States, and on that account, because of the necessity for the coordination of State legislation with the Federal legislation, it has seemed to me that it would be the part of wisdom to have a bill such as S. 5, the Copeland bill, assume the from of an amendment to the existing law.

The other point that I would like to make is, and that has been touched upon by the previous speaker, who apparently does not share the same idea that I do, the matter of the Federal Trade Commission. It would seem as though the trend of the times was to provide legislation that would go into the field of advertising and restriction in the regulation of advertising beyond the limits of the industries now under consideration. In the belief that appears to be inevitable, it would seem as though ultimately one commission or one source of jurisdiction for such matters could be anticipated now and set up. It would be rather deplorable, I should think, for the whole of advertising, cutting as it does a cross section through all different industries, to be so distorted as to have it appear for its appeal and for its consideration before innumerable committees for the innumerable industries. To that extent, it seemed to me as though the Federal Trade Commission did exist as an institution set up and now practically prepared and equipped to function to accomplish that end for all advertising.

However, in saying that, I am in full accord with the idea Senator Copeland has expressed that the matters primarily concerning the food, drug, and the drug administration department should of course have provision made for hearings through them first.

Senator COPELAND. I may say, so far as I am concerned, and I know that that is the feeling of the Department that that should be so.

Mr. BRISTOL. The only point involved—that would be for me as a manufacturer, other than a legal interest, involves that broad field of advertising. It is my responsibility in my own company to assume the responsibility for our advertising promotion, and when you get into the field of advertising, assailed as it is from so many standpoints, it seems only fair that we give cognizance to the fact that matters

that do not endanger public health but become matters of private and individual and divided opinion should be subject to consideration as matters of opinion. That is the reason for my desire, as a manufacturer, that the advertising and matters involving private opinion or places where individual opinion will differ, shall be tried on a basis where fair consideration may be given to the possibility of the difference of viewpoint, particularly where it does not involve or jeopardize the public health. It is due to the fact that there have been so many attacks on the various phases of advertising from innumerable sources, including the Government itself, that we, as taxpayers, have had the privilege and embarassment of being assailed by our own organization, supposedly, our Government. It is our desire to say that matters of opinion be left in the field where fair and adequate consideration may be given.

In closing, I just want to say this, Senator. Contrary to any expressed opinion that you may hear, I, for one, and I know scores of others, want to see this legislation that will be effective and fair. We are going to live with it for a long time, and I leave to the lawyers technicalities of accomplishing that, but I want you to know that we are for legislation and we hope it will go through in this session.

I thank you.

Senator CLARK. Miss Edwards. I think, Miss Edwards, that you represent one of the several affiliated organizations on this matter in which several representatives were to be heard briefly?

Miss EDWARDS. There are a number of representatives to be heard, and we have planned the program so that two people will make the major presentations, so as to abbreviate the whole presentation.

STATEMENT OF ALICE L. EDWARDS, EXECUTIVE SECRETARY, AMERICAN HOME ECONOMICS ASSOCIATION, WASHINGTON, D. C.

Miss EDWARDS. Mr. Chairman and gentlemen, the American Home Economics Association is a professional organization of trained home economists, and its object is the improvement of the standard of living in the home and community. Branches of the association are organized in each of the States, the District of Columbia, Puerto Rico, and in Nova Scotia and Alberta, Canada. The membership of the association includes teachers in colleges, universities, elementary and secondary schools, leaders of rural home-extension groups, institution managers, social workers, and homemakers.

Members of the association because of their training and experience are keenly aware of the benefits and protection which consumers have derived from the enactment and enforcement of the Food and Drugs Act of 1906. However, they have long realized that this act is inadequate in meeting present needs.

While home economists are concerned primarily with foods and the safeguards necessary to insure the quality and honesty of these products, they also recognize the importance to health and good grooming of safe and reliable drugs and cosmetics. They would particularly stress at this time the importance of those provisions which aim to prevent economic deception of consumers. The majority of our people can maintain a fair standard of living only by exercising careful choice in their expenditures. In the fields of foods, drugs, and cos-

metics their deception and exploitation through false and misleading advertising, through deceptive packaging, through lack of adequate information actually misbrand, results in the misuse of thousands of dollars. This sum, if wisely spent, would not only improve the health and happiness of thousands of families but would prove a great stimulant to sound agriculture, industry, and trade.

Our studies of consumers' problems have made us keenly aware of certain problems of production and merchandising which confront the manufacturer, distributor, and advertiser. We have no desire to cripple or destroy sound business for, as consumers, we are dependent upon these groups for the goods we wish to buy. We are convinced that their interests and ours will be best served if certain unethical practices of the less scrupulous members of these business groups are brought under control. This bill, with the amendments proposed, would, we believe, go far toward correcting these practices.

May I say that I have made no statement in this presentation of the special amendments which we wish made in S. 5 (Committee Print No. 3). To save your time, Mrs. Baldwin, the representative of the National League of Women Voters, will present amendments desired not alone by her own organization but by the American Association of University Women, American Dietetic Association, American Home Economics Association, American Nurses Association, Girls Friendly Society of the U. S. A., Medical Women's National Association, National Board of the Y. W. C. A. of the U. S. A., National Congress of Parents and Teachers, National Women's Trade Union League, and Women's Homeopathic Medical Fraternity, all of which organizations are to be represented at this hearing.

Senator CLARK. Mrs. Bannerman.

STATEMENT OF MRS. MARY T. BANNERMAN, CHAIRMAN COMMITTEE ON LEGISLATION, NATIONAL CONGRESS OF PARENTS AND TEACHERS, WASHINGTON, D. C.

Mrs. BANNERMAN. Mr. Chairman and members of the committee, on December 7, 1933, 15 months ago, only a very few national organizations representing the consumer appeared before this committee in support of the Copeland Federal food and drug bill. By the last of February 1934, when hearings were reopened, public sentiment has so developed that leaders of national organizations representing several millions of consumers appeared in its support. As a result of careful study of the provisions of the bill and of existing conditions which have made necessary these provisions, several additional consumer organizations have now joined the growing army of supporters. The rapid growth of sentiment for this legislation is due in large measure to an increasing distrust of the failure of the product advertised to measure up to the sales recommendation made for it. People are coming to realize that they have a right to know the truth concerning their purchases, that they have a right to foods which are clean and unadulterated, and that their claims are justifiable.

Studies in home-making which have been in progress by lay and professional organizations over a period of several years have developed consumer consciousness and created an intelligent demand for higher grade products truthfully advertised. The interest of producer, as well as consumer indicates that this demand should be

recognized and efforts to meet it be encouraged, both by protective legislation and by voluntary effort. In many of these national organizations, health, both of children and adults, is a major objective. The Food and Drugs Act of 1906 has helped much in maintaining better health standards than those prevailing prior to its enactment. Its inadequacies, however, in preventing false and misleading advertising, in including cosmetics, and in failing to provide adequate and truthful information to guide consumers in purchasing wisely, have long pointed to the need for a new law. This bill (S. 5) now under consideration, we believe, meets that need. In some respects it is a decided improvement over the bill which was before Congress last year. However, we are convinced that it would be greatly strengthened if provisions were included requiring (1) graded standards of food, (2) a listing of ingredients on the labels of foods, drugs, and cosmetics, and (3) prohibition of exportation of adulterated foods, drugs, and cosmetics.

We believe that it is not unreasonable to ask that printed advertising be truthful. In fact, the ultimate result of dependable advertising should be to increase rather than to diminish sales. We believe, also, that it is in the interest of producers as well as consumers that radio advertising shall not be an offense either to our credulity or to the average level of those sensibilities which constitute good taste.

Speaking for our own organization, the National Congress of Parents and Teachers, an organization having a paid membership of approximately a million and a half, in 48 States, Alaska, and Hawaii, for more than 30 years, promotion of child health has been one of our major projects. Organized committees on this subject are functioning in nearly all of our more than 20,000 local associations. Obviously, the success of our work in this field demands proper protection against impure, poisonous, and adulterated foods, drugs, and cosmetics, together with truthful advertising and informative labeling of these products.

In September 1933, the National Congress of Parents and Teachers first endorsed S. 1944, Seventy-third Congress. Later we accepted the substitute, S. 2800, and deeply regretted the failure of its enactment into law last year. The Copeland bill was endorsed in the resolutions adopted at our national convention last May, and it was in the legislative program for 1935 adopted by our board of managers in Niagara Falls in September. Requests from State branches of the National Congress of Parents and Teachers are being received daily seeking the status of the Food and Drugs Act and asking when action on it may be expected. Together with the professional organizations of home economists and with other consumer organizations, we earnestly request that prompt and favorable consideration be given this legislation by your committee and that its passage in the Senate be expedited by every possible means.

STATEMENT OF MRS. HARRIS T. BALDWIN, FIRST VICE PRESIDENT, NATIONAL LEAGUE OF WOMEN VOTERS

Senator CLARK. Mrs. Baldwin, will you state your name, the organizations you represent, and so forth, so that the reporters will be able to get it?

Mrs. BALDWIN. My name is Mrs. Harris T. Baldwin, I am first vice president, National League of Women Voters.

Mr. Chairman and members of the committee, the National League of Women Voters wishes to express its gratification at this time at the introduction of this bill S. 5 into this session of Congress. We know that there is a continued interest among our membership in such legislation, and there is also a great demand for an early passage of legislation which will revise the Food and Drugs Act in the interest of the buying public.

It seems to us that S. 5 is one of the most promising pieces of legislation now in sight in the interest of the buying public. We feel that it has very important gains over the present Foods and Drugs Act in that cosmetics are included under this, in that the advertising of foods, drugs, and cosmetics is placed under regulation and it had more effective administration procedure provided.

We should like to emphasize how important we think it is that the administration of the regulations governing advertising be kept under the Department of Agriculture and the Food and Drugs Administration, because we think that false advertising of goods, drugs, and cosmetics is a very serious offense against the public interest.

We think that it must be dealt with promptly, with the opportunity to prosecute offenders, if necessary, without delay. If the regulation of this were placed under the Federal Trade Commission false advertising would be classified as an offense against competitors, which could be dealt with only by the slow process of investigation, hearing, cease and desist orders, and appeal to the courts to uphold the order.

While we think that there are very many important gains over the present food and drugs bill, we do think that there are some provisions in the Committee Reprint No. 3 which do not appear to be in the public interest, and if I may I would like to call you attention to those.

The first one is on page 7, section 302, line 16, in which you have stricken out all of section 8(h). It seems to us that the amended provision does not require any indication of quality to be placed on the label of standard foods. It does seem to us that if there is no indication of what is in the can, or what is in the package of standard brands, that there is nothing there to indicate that the food is standard, under the law.

Senator COPELAND. May I interject?

Mrs. BALDWIN. Yes; Senator Copeland.

Senator COPELAND. The Department sets up standards of quality and fill.

Mrs. BALDWIN. Yes; we understand that.

Senator COPELAND. Now, then, if a product is found on the market which does not meet that standard, then the manufacturer is in trouble.

Mrs. BALDWIN. Yes; but on the other hand, as I understand this section there will be nothing at all on the label to indicate that what is in the can or package meets the standard set by the Government. Would this provision require that the product although unlabeled to that effect would have to meet the standard under the law?

Senator COPELAND. I would think so, because you take in the case of ice cream, there is, first, the standard of identity, that an article cannot be sold as ice cream unless it contains 6 percent butterfat, and the other requirements; then a standard of quality is established.

It means, then, that no article could be sold as ice cream unless it meant that standard of quality.

Now, of course, we have left to the advertiser the opportunity to brag about his article being a higher standard and having a higher percentage of butterfat, and so forth. So I believe, if I may be permitted to say it, that the very fact that it is sold on the market is an evidence that it meets that standard of quality, and if it does not and that is severed, then, of course, the manufacturer is in parts.

Mrs. BALDWIN. May I ask a question?

Senator COPELAND. Yes.

Mrs. BALDWIN. Is there then something on the ice cream that shows that it is standard, under the law?

Senator COPELAND. I am not sure about that. It must be said here that this label must bear a statement that it falls below such a standard of quality, if it does fall so below that standard of quality. We feel, therefore, if this is sold as ice cream, that is evidence that it does meet that standard, and then if it is below the standard but still above the standard of identity, it would have to say, "This is below standard." The label would have to carry that information.

Mrs. BALDWIN. We, of course, buy a great many things on the market today by brand names. We do know that there is a standard, and below that standard those things cannot be sold but when we buy by brand names we do not know its quality unless there is something on the label that tells us about the standard of quality and the ingredients, and so forth.

Senator COPELAND. Certainly no manufacturer would be willing to put on an article and say, "This is below standard", but he would be required to do that. If he did sell an article which was below standard it would have to be stated on the label that it was below standard. Therefore, you may assume that when you buy that article that it is standard. Then the advertiser may say "Well, ours is way above standard." That is where he has his opportunity.

Mrs. BALDWIN. Of course, there are foods sold, are there not, that are not injurious to health but are below standard of certain qualifications?

Senator COPELAND. You take in canned peaches, the standard requires a certain size of peaches, so much sugar in the sirup, and so forth. If a brand of peaches does not meet those requirements it would have to be labeled "below standard." So I believe, really, that there is a misapprehension about that. I think you have possession there as regards the standard foods.

Mrs. BALDWIN. We wished to bring that up and try to clear it up.

The next one is on page 8, section (1). We think that this section has been very much strengthened by deleting the permission to file the ingredients of food, for which no standard of identity is prescribed. We believe it has been weakened somewhat by providing the name only of the ingredients be given, striking out "in order of predominance by weight." Many of these things, we think, have been strengthened, Senator Copeland, but there are little weaknesses here and there.

Senator COPELAND. I might say, in that connection, if I may, that it is very important, because we have what we call allergy. People are susceptible to one thing or another. The value of this is that it gives the names of the ingredients so that if some person knows

he is allergic to a given substance, the statement on the label gives him that information.

Mrs. BALDWIN. We are very glad that the ingredients are to be given.

On page 9, section 303, we ask another change. This section still permits the establishment only of a reasonable standard of quality of food. We are very glad of that, but we are still hoping that this could be amended to read "standards" instead of "a reasonable standard," because we are looking forward to the day when there will be grade labeling on the food products which we buy in stores.

Senator COPELAND. We want to leave something, you know, for your successors to carry on.

Mrs. BALDWIN. But we would like to start them well on their way.

The next one is section 401, on page 13, subsection (b), line 22. We think that the change in line 22 weakens this section, since it will not be necessary to note on the label of a drug recognized in an official compendium any variation from the definition and description given.

Senator COPELAND. I want to say to the lady if she will bring us some language that will make it possible to show that, we will give her a prize. We have worked over that more than anything else, and we finally decided that this is just the best that we could do. If you have something better, you bring it up here.

Mrs. BALDWIN. Whether I can or not, I do not know. Anyway, may I register with you that we wish line 22 reinstated in the bill.

On page 16, section 402, line 20, subsection (e). We think that this section is also strengthened by deleting the permission to file the ingredients of drugs not in the official compendium with the Secretary of Agriculture. It is weakened by the omission of the requirements that the quantity or proportion of ingredients must be given on the label. We think this is particularly serious in the question of drugs.

The next one is on page 20, section 501, and has to do with cosmetics. We liked very much better the first phrasing which you had, when you said that a cosmetic was adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to the user under the conditions of use. We thought that covered the situation very well.

There is a question in our minds about "injurious to health." We wondered if you would consider it injurious to health if a person used a cosmetic which had caustic properties and which burned off the eyebrows. We wondered whether that would be injurious to the person or injurious to the beauty of the person. That thing has happened, and we are very anxious to see that we are protected from such happening again.

Senator COPELAND. Of course, the example that you give shows that it would be injurious to the eyebrow; it would destroy it.

Mrs. BALDWIN. Yes.

Senator COPELAND. Now, the question is, is it a substance which would also damage the skin and in that way do harm. In that case it would be injurious to health.

Mrs. BALDWIN. If it damaged the skin?

Senator COPELAND. Yes.

Mrs. BALDWIN. If hair falls out, would it then be injurious to health?

The next one, Senator Clark, is section 502 on page 22, which has to do with the quantity in terms of weight, measure, and numerical count of packages. We wondered why it was necessary to include "and soap" in that. We could see no reason why labels for soap should not be required to give the quantity of contents just as other cosmetics would have to give similar information.

Senator COPELAND. The only reason I am not making any comment is I do not wish to take the time of the committee, but if an exemption is made to soap it would be to ordinary toilet and household soap. It would be made very clear in the report, if it is a medicated soap with claims for pure, it would come under the requirement of the bill, because it becomes a drug.

Mrs. BALDWIN. It does not say so in here.

Senator COPELAND. I think you will find it is very clear, as it is proposed on page 2, line 17 [reading]:

> The term "cosmetic" includes all substances and preparations, except ordinary toilet and household soap.

So, when it comes to medicated soap, then it comes under the line of drugs.

Mrs. BALDWIN. Thank you, Senator. As in the case of foods and drugs, the user needs to know what ingredients are in cosmetics in order to select those free from substances which have proven harmful to her.

We urge that a new paragraph be added to section 502 just after paragraph (c), as follows:

> (c) If its label fails to bear (1) the common or usual name of the cosmetic, if any there be, and (2) in case it is fabricated from two or more ingredients the common or usual name of each such ingredient be listed in order of predominance by weight.

Now, on page 23, section 503, it would be better, we think, to restore this section, permitting the establishment of tolerances for poisonous ingredients in cosmetics, because while section 501 rates a cosmetic as adulterated if it contains a poisonous substance, there is a question as to how great a quantity of such a substance may render it injurious to health. We could not see that it provided for the establishment of those tolerances, and we do know that you can include in a cosmetic a certain amount of poison.

Senator COPELAND. You have made special reference to section 503. Did you mean to do that? That is on page 23.

Mrs. BALDWIN. That is the one that previously set up tolerances, and we think we should like to see that included in the bill.

Senator COPELAND. You would like to have the old language restored?

Mrs. BALDWIN. Yes, Senator.

Senator COPELAND. Well, of course, that is covered by the general term that it should be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. So the Department itself would have to determine whether there was too much of this or that poison in the cosmetic, if there is any there.

Mrs. BALDWIN. Then I have one more, and that is on page 50, section 714, and which has to do with the export of adulterated foods and drugs. As this is drawn up, the United States manufacturer may export foods, drugs, and cosmetics to any country; provided, as I understand it, the laws of that country would permit the acceptation of those exports. That, as we feared, would permit this country to

export adulterated foods, drugs, and cosmetics. I am afraid I still shudder over the testimony that appeared before you last year in the question of the wormy figs. I think about those every once in a while. We realize that most of the European countries do have food and drug laws, and that a good many South American countries have, but many of the eastern countries and the oriental countries have laws which do not protect the people who would buy, and we should like very much to see this clause strengthened so that the reputation of American goods may not be injured by the exporting to other countries of distinctly inferior products.

Again may I say how delighted we are that you have introduced this bill, and we hope that it will soon be passed.

Senator CLARK. Mrs. Barber.

STATEMENT OF MRS. ALVIN BARBER, AMERICAN ASSOCIATION OF UNIVERSITY WOMEN

Mrs. BARBER. Mr. Chairman, today I have the privilegee of apparing before the members of your committee a second time as a representative of the American Association of University Women, to express to you again the very lively interest of the members of that association in an adequate revision of the Federal Food and Drugs Act and also their undimmed hope for a prompt reporting out of committee of a bill to achieve such revision.

The American Association of University Women is an organization of 43,000 members holding degrees from accredited colleges and universities and of 40,000 associate members with 2 or more years of college training. Their national head is Miss Meta Glass, president of Sweet Briar College, Virginia. This organization is actively interested in the welfare of the American home and has for years maintained a national committee for the scientific study of consumer goods with a view to establishing and maintaining quality standards for products of all types used in the home. Its members are therefore keenly conscious of the gaps and inadequacies which time and change have developed in the present Food and Drug Act, especially in regard to the cosmetic industry, which has grown to maturity since 1906.

During the year which has passed since this association first expressed to you its earnest support of a new food, drug and cosmetic act, the members of its several hundred branches throughout the 48 States have continued their study of the needs for such legislation and are now more than ever convinced of the pressing call for action. It seems to them both deplorable and unnecessary that legislation so obviously and immediately needed to protect the health and pocketbooks of 122,000,000 people should be longer delayed. It seems to them especially shocking that, because of the unrestricted sale of cosmetics at this time, preparations which more than a year ago were demonstrated before you by the Food and Drug Administration as desperately dangerous and often fatal in use, are still freely sold in drug stores, beauty parlors, and barber shops throughout the United States. Mr. Chairman, these women urge upon you a recognition of the immediate need for legislation to prevent such sales as well as to correct the many other inadequacies of the present act.

In closing may I assure you of the conviction of this association that any revision of the Food and Drugs Act that your committee may

recommend will be a revision for the protection of the consumer, not primarily a revision for the protection of the producer, distributor, advertiser or publisher. The consumer is inarticulate, the representatives of these industries are not. Yet, it is self-evident that if the consumer is properly protected, all honest and scrupulous business will be protected too. Thank you.

Senator CLARK. Miss Eichelberger.

STATEMENT OF MARIETTA EICHELBERGER, AMERICAN DIETETIC ASSOCIATION

Miss EICHELBERGER. Mr. Chairman, the American Dietetic Association has a membership of 2,500 professionally trained women who are engaged in the following types of work: As resident or extension teachers of food and nutrition; dietitians in hospitals, schools, or other institutions; owners or directors of inns, tearooms, and cafeterias; or as home economics specialists representing a housewife's viewpoint with manufacturers and distributors. Holding such positions, these women are responsible for the selection, purchase, preparation, and service of foods to thousands of people. Representing such a large group of the consumer public, the members of the American Dietetic Association desire the speedy passage of the food, drugs, and cosmetic bill, S. 5, Committee Print 3. Thank you.

Senator CLARK. Miss Eastman.

STATEMENT OF ELIZABETH EASTMAN, NATIONAL BOARD OF THE YOUNG WOMEN'S CHRISTIAN ASSOCIATION

Miss EASTMAN. Mr. Chairman and members of the committee, I represent the National Board of the Young Women's Christian Association of the United States of America.

At their last convention, in May 1934, the Young Women's Christian Associations, represented by about 2,000 delegates, voted to aid in the organization of the consumer and to support whatever legislation would help the Government to raise the economic level of the country. As one way of interpreting this action, the national board has authorized us to work for the principles of this bill. Our 600,000 members in every State in the Union are consumers who wish their Government to protect their safety and health in the use of cosmetics and drugs, as well as in the use of food. As home makers, they wish their Government to guarantee such standards in food that they will get full value for their expenditures and will know what they are buying.

May I add, Mr. Chairman, that the Young Women's Christian Association does not officially endorse the use of cosmetics, but it is part of the program of almost all women, I think you will agree, that anything that adds beauty and color to life is a good thing. I think that you would be interested to know of the report that I have received from the girls in our association who were voluntarily asking for study clubs, in order to study this whole question as consumers, most of them with very little money to spend, and they have asked me to give you this message from them, that they are looking to you and to their Government to protect their lives.

Senator CLARK. Thank you. Miss Maule.

STATEMENT OF MARGARET C. MAULE, GIRLS FRIENDLY SOCIETY, UNITED STATES OF AMERICA

Miss MAULE. The board of directors of the Girls Friendly Society, representing a membership of 30,000 women and girls, has endorsed the revision of the Food and Drugs Act which will bring cosmetics under the provisions of the act, which will provide for standardization of food products and which will control advertising. As consumers, we are affected by the provisions of the act and we urge that the revisions be approved, in the interests of the consumer. Thank you.

Senator CLARK. Dr. Kain.

STATEMENT OF DR. HELEN GLADYS KAIN, MEDICAL WOMEN'S NATIONAL ASSOCIATION

Dr. KAIN. My name is Dr. Helen Gladys Kain. I represent the Medical Women's National Association. This association is composed of women physicians in all the States of the Union and organizations in many of the large cities. I represent that group, and it is a very representative group.

At the meeting held last June of the American Medical Association, they voted to endorse such legislation concerning cosmetics and drugs as is being put forth in this bill, S. 5, for the protection of the women and the people in the United States.

Senator CLARK. Miss Noyes.

STATEMENT PRESENTED BY MISS ELIZABETH EASTMAN FOR THE AMERICAN NURSES' ASSOCIATION

Miss EASTMAN. Mr. Chairman, may I present this statement, signed by the president of the American Nurses' Association for Miss Noyes who is unable to be present this morning?

The American Nurses' Association composed of 110,000 graduate nurses is deeply interested in the efforts now being made to amend the present Food and Drug Act and is prepared to support S. 5 (Committee Print 3) believing that through its provisions the consumer will be more adequately protected. Nurses as a group are in a better position to observe the effects of food and drugs than any other professional group both in the home and the institution for it is they who feed the patient and administer the medicine. They are, therefore, deeply desirous that every possible protection should be provided to both the sick and the well at all times but most especially in connection with these particular necessities of life.

Respectfully submitted.

SUSAN C. FRANCIS, *President.*

Senator CLARK. Have you another statement to present, Miss Eastman?

STATEMENT PRESENTED BY MISS ELIZABETH EASTMAN FOR THE NATIONAL WOMEN'S TRADE UNION LEAGUE

Miss EASTMAN. Yes. This is a statement from the National Women's Trade Union League of America, signed by the secretary-treasurer, Elisabeth Christman:

The COMMITTEE ON COMMERCE,
United States Senate.

GENTLEMEN: The National Women's Trade Union League of America represents the organized women workers of the country. Our affiliated membership numbers about 500,000 most of whom are wage-earning women. Revision of the Food and Drugs Act receives our hearty endorsement as there is no group in the country more immediately interested in the results of such a revision.

To women who have the spending of limited incomes it is of vital importance that the food and drugs they purchase are unadulterated and pure, and that standards of quality are recognized and indicated. The cosmetic industry has become one of the leading industries in the country and is almost entirely patronized by women. It is absolutely essential that the selling of cosmetics should be regulated so that the purchases can be assured that her money is not being wasted on products that are a menace to health. Fraudulent and misleading advertising should certainly be controlled in the interest both of the consumer and of public health.

If these ends are to be secured it is essential that an administrative procedure be guaranteed that will make certain enforcement of the provisions of the bill. For this reason it is important that the Department of Agriculture have control of the administration of the regulations in the bill so that there shall be no divided authority in dealing with the provisions of the bill and so that enforcement shall be immediate.

There are certain aspects of this bill which do not altogether meet with our approval, but as these are being discussed in detail by the representative of the National League of Women Voters, who is appearing at this hearing, we will not take the time to enumerate them. We assure you, however, that we are in full accord with the criticisms made and amendments suggested by her.

We urge that the committee report this measure out as promptly as possible as it is essential in the interests of the purchasers of food and drugs and cosmetics in this country that they receive the protection of an amendment to the Food and Drugs Act during the present session of Congress.

Respectfully submitted.

ELISABETH CHRISTMAN, *Secretary-Treasurer.*

Senator CLARK. Dr. Green.

STATEMENT PRESENTED FOR DR. JULIA M. GREEN, WOMEN'S HOMEOPATHIC MEDICAL FRATERNITY

Miss EDWARDS. Speaking for Julia Minerva Green, representing the Women's Homeopathic Medical Fraternity.

Dr. Green, because of her professional duties, has found it quite impossible to be present this morning. She asked that a statement be made to the effect that the Women's Homeopathic Medical Fraternity is heartily in favor of the proposed food and drugs bill, with the amendments and changes which were presented to you by Mrs. Baldwin a little whole ago. This organization of medical women is convinced, from the experience of its member, of the need for a bill such as that proposed and urges its early enactment.

Senator CLARK. Mr. Hibben.

STATEMENT OF ROBERT C. HIBBEN, EXECUTIVE SECRETARY OF THE INTERNATIONAL ASSOCIATION OF ICE CREAM MANUFACTURERS, WASHINGTON, D. C.

Mr. HIBBEN. My name is Robert C. Hibben, executive secretary of the International Association of Ice Cream Manufacturers, 1105 Barr Building, Washington, D. C. This association is composed of 487 ice-cream companies, operating 1,200 ice-cream plants in the United States. An analysis of our membership sales gallonage, compared with the 1933 report of ice-cream production of the Bureau of Agricultural Economics, United States Department of Agriculture, shows that our members are manufacturing over 70 percent of the wholesale production of ice cream in the United States.

An analysis of our membership by numbers shows that 70 percent are in the medium or small class, manufacturing less than 100,000 gallons per year and 53 percent of our members manufacture less than 50,000 gallons per year.

The board of directors of the international association have frequently gone on record endorsing fair and practical ingredient and sanitary standards for the manufacture and distribution of ice cream. Some 10 years ago we were in negotiation with the Federal Food Administration in an endeavor to establish a national standard for ice cream. While this was unsuccessful the board of directors of this association are still in favor of a national standard for ice cream, which is heartily endorsed by the membership, and it is our hope that S. 5, the bill now under consideration, will give us the opportunity of securing this standard.

At the time of the previous negotiations with the Food Administration there was a great lack of uniformity in State standards for ice cream. It was at the suggestion of Dr. Campbell that the association through its committee on definitions and standards, sanitary control committee, and the research committee, prepared suggested State standards. This endeavor of the association resulted in a suggested sanitary law approved by the sanitary control committees of the International Association of Dairy and Milk Inspectors and this association, a suggested ice-cream standard and a plant manual for use of members in carrying out the provisions of these standards and regulations. This endeavor on the part of the international association has been used as a basis for many new State standards and several city ordinances.

In the manufacture of ice cream certain ingredients entering into its manufacture have a tendency to lose their natural color and it has been the custom since the start of the ice-cream industry to use harmless colors to bring back the natural coloring of the ingredients in this product. The most outstanding example is the important flavor, strawberry ice cream. All ice cream manufacturers use large quantities of fresh strawberries in this flavor and it is one of the most popular flavors in the sales program, ranking third, vanilla being first and chocolate second. However, strawberry ice cream without a few drops of harmless coloring to a 100-pound mix would result in a product that would be unsalable. This is true in other flavors, such as peach, cherry, raspberry and orange.

Therefore, it is the opinion of the ice-cream industry that paragraph k of section 302 appearing on page 9 of the committee's reprint requiring color to be stated on the label will work a hardship on the ice-cream industry. In paragraph d of section 301 on page 5, harmless coloring is permitted in the manufacture of ice cream. In all State standards for ice cream harmless coloring is permitted.

The act of March 4, 1923 (U. S. C., title 21, sec. 6; 42 Stat. 1500, ch. 268), referred to on page 52 of this bill which established a national standard for butter, permits the use of color in butter without statement on the label. Ice cream is a dairy product the same as butter and to permit butter to be manufactured with color with no mention on the label and requiring ice-cream manufacturers to label their product when harmless colors are used, we believe is unfair discrimination between two important dairy products.

We believe such discrimination will work a hardship on the ice-cream industry as housewives and other consumers have purchased ice cream over the past 50 years without any mention of the harmless color on the label and if this bill is passed and mention is required on the label, we believe sales resistance would be created for commercial ice cream. Housewives not seeing it appear on the label previously will believe that some new ingredient has been added artificially which is untrue.

Ice-cream sales in 1933 were only 56.75 percent of 1929 sales. Sales data for 1934 now being compiled will show some improvement over 1933. It has been accurately estimated that if the ice-cream industry can regain this lost gallonage that it will be a large factor in absorbing the troublesome surpluses of the dairy and fruit farmers in the United States. In other words, the recovery of the ice-cream industry back to a normal sales basis will be a direct benefit to agriculture.

Therefore, we offer for the committee's consideration the following amendment to paragraph k of section 302, on page 9, which now reads:

> If it bears or contains any artificial flavor, artificial color, or chemical preservative, and it fails to bear a label stating the fact—

adding the following amendment:

> except that in the manufacture of ice cream artificial color may be used without statement on the label where in the manufacturing process the natural ingredient color is diminished.

It is evident that the above amendment does not permit the use of harmless color without statement on label in any way to cover up any inferiority but rather to only bring out the natural coloring of the ingredients going into ice cream.

We have endeavored in all our activities with standards to cooperate with the Federal Food Administration and the different State administrations handling our product, and in an informal conversation with Dr. Campbell after receiving your committee's reprint, I discussed the use of harmless color in ice cream. I have Dr. Campbell's permission to quote him as follows: Dr. Campbell stated he was not in sympathy with the use of color in any food without the statement on the label. However, he said as a matter of logic there was as much reason for the extension of the requested concession to ice cream as there was to butter.

It is the hope of the ice-cream industry that your committee will give serious consideration to the above amendment which we believe will eliminate a factor causing great sales resistance and prevent the recovery of this industry which in turn will be a detriment to both the dairy and fruit farmers in the United States.

Senator COPELAND. Mr. Hibben, does your criticism relate wholly to strawberry ice cream?

Mr. HIBBEN. No, sir; the same is true in peach, raspberry, cherry, orange, and practically all the fruit and nut flavors.

Senator COPELAND. Thank you.

Senator CLARK. Mr. Stude.

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STATEMENT OF HENRY STUDE, PRESIDENT AMERICAN BAKERS ASSOCIATION

Mr. STUDE. The bill provides for a committee of seven on food standards, of which two are to be from the food producing, processing, and manufacturing and distributing industries. We should like to suggest that instead of two that provision be made for a panel of representatives of food industries. We do not believe that any two men have as wide experience and knowledge as is contemplated may be needed.

Senator COPELAND. That is, your idea would be that when the matter you were interested in was under consideration that two from that industry should be included?

Mr. STUDE. Yes.

Senator COPELAND. When the matter of ice cream is considered, then two from that industry should be included in the panel?

Mr. STUDE. Yes; the same as in the canning or the meat industry, and so forth, so that the members of the industry would have knowledge of that problem.

By this suggestion there would be brought to the aid of the Secretary a large number of men with a wider field of knowledge and experience and he could select two members from the panel depending upon the type of business or the problem before the Committee.

Paragraph (k) on page 9 prohibits artificial flavoring and artificial coloring. We believe provision should be made to permit such coloring and flavors in icing in decorating a cake. If a baker makes a birthday cake and wants to use colors in the icing and decoration, we believe he should be permitted to do so, provided of course that they are approved flavors and colors.

Paragraph 5 on page 3 contains the word "opinion." We believe this will create difficulty. A baker may in his advertising express an opinion about his product. He may claim it is good bread. Others may dispute this. Since its goodness is determined largely by a matter of taste and since in a matter of taste there is no dispute, the wide difference of opinion in baked products becomes apparent.

On page 10, line 3, it provides for fixing a standard of quality. We submit that this is practically impossible in the baking industry. In the making of baked products the ingredients are mixed, molded, proofed, and baked, all of which consists of the art and science of baking; and the resultant product or its acceptance by the consumer is the result of these operations.

Let me illustrate: A hotel will set before its patrons a tray of baked products. You will find there a hard, crisp roll. It is made of flour and water and yeast and salt. Alongside of it you will find a Parker House roll. Its ingredients are flour, water, yeast, salt, shortening, sugar, milk, and eggs. From the standpoint of ingredients alone the Parker House roll might be said to be a superior quality and yet many prefer the crisp roll. It is a matter of taste rather than a matter of quality.

A baker is like a cook, the quality is determined by the use of ingredients rather than by ingredients alone. Give 6 cooks 6 chickens and 6 pots, with instructions to make 6 chicken stews; they will all be of equal quality from the standpoint of ingredients, but the resultant product from the standpoint of taste may differ widely.

The bill provides that no standard of quality shall be established for any fresh natural product. We submit it is much easier to define quality meat than to define quality bread. If the ingredients are pure, clean, wholesome, and there is no misrepresentation, we believe the public interest is served.

Senator COPELAND. May I ask a question?

Mr. STUDE. Yes.

Senator COPELAND. In reference to your plan, which strikes me as a very excellent one, for the provision of these panels, under the provisions of section 303, definitions of standards, all these matters that you spoke of could be given consideration, could they not?

Mr. STUDE. Yes, sir.

Senator COPELAND. In the establishment of standards?

Mr. STUDE. Yes, sir.

Senator COPELAND. That would answer your suggestion, would it not?

Mr. STUDE. Yes, sir. The same paragraph also provides for a standard of identity. Baked products are made to fit a taste and the same pattern does not fit all tastes. For example, what is rye bread? Rye bread is bread made from white and rye flour and the amount of rye flour added depends upon the taste of the consumer of that particular market or locality. It is geographical and racial.

At our bakers' school we had a young man from Germany and I once asked him how much rye flour was included in German rye bread. And his answer was, "What part of Germany?" Apply that to the United States and you have an example of the difficulty of developing a standard of identity.

Page 8, line 8, provides that where a product has two or more ingredients, the name of each ingredient shall appear on the package or label. We submit that this will create difficulty and be an added burden to the baking industry. In the case of pan bread which is sold wrapped, malt sirup is sometimes used. Its use depends upon the condition of the weather during the ripening of the grain and sometimes the locality where the wheat is grown and sometimes the condition of the harvest. Wheat from different sections may or may not require malt extract. The baker would, therefore, have to be continually changing his labels or wrappers, with the added expense. More than 20,000 units in the industry sell the bread to the consumer direct at the place of manufacture. These small retail neighborhood bakers produce a variety of products. If they must attach a label to each variety of product containing the full list of ingredients, it will add to their difficulty and provide a rather large number of cumbersome labels.

Senator COPELAND. You are referring now to page 8, subsection (i), are you not?

Mr. STUDE. Yes, sir; that list of ingredients.

Senator COPELAND. And now if you will read back in the beginning, "if it is not subject to the provisions of paragraph (g)" and going back to paragraph (g) you will find, "if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation," and so forth. If your panel proposition were carried out and you had to establish the standards for bread, then paragraph (i) would not apply.

Mr. STUDE. Then it would be called bread or a standard of bread, and then you would not have to put the ingredients on the label.

Senator COPELAND. Yes.

Mr. STUDE. In case of the Parker House roll just referred to the difficulty of properly labeling that is apparent, whereas in the case of a mince pie it will probably require the entire top surface.

I trust the committee will understand that these are merely suggestions. They are offered in anticipation of difficulties that may arise in conforming to the bill as written. It is in no sense intended as an objection to the bill and its purpose. The baking industry has always subscribed to any law that seeks to bring to the consumer pure, clean, wholesome food and provides protection against misrepresentation.

MEMORANDUM BRIEF OF AMERICAN BAKERS ASSOCIATION ON SENATE BILL NO. 5 (COMMITTEE PRINT NO. 3), A PROPOSED FEDERAL FOOD, DRUGS, AND COSMETICS ACT SUBMITTED AT A HEARING ON THE SUBCOMMITTEE OF THE SENATE COMMERCE COMMITTEE, MARCH 2, 1935

The American Bakers Association is a national organization representative of the baking industry of the country with members in every State of the Union and on its behalf I beg to submit the following:

We think it unfortunate, particularly in view of the new powers granted by the bill as opposed to the present Food and Drug Act and the broadening of its subject matter to include cosmetics, that the opportunity is not embraced at this time to treat food in a separate bill, and drugs and cosmetics in a separate bill. If the bill were merely a proposal to amend the present Food and Drug Act we could see that perhaps such a change of treatment might be impracticable, but inasmuch as a totally new bill and treatment of the whole subject is now being proposed we are convinced that real progress could be made in this type of legislation by writing one bill for food and another bill for drugs and cosmetics.

The following considerations have caused us to reach this conclusion.

The purpose of, and the ultimate legal justification for, legislation of this type is conceded to be the accomplishment of substantial and beneficial results to the public and in this particular type of legislation the substantial and beneficial results to the public are two, namely, (1) the protection of public health and (2) safeguarding the public as far as possible from fraud and deception. We believe that these two objects are adequately accomplished under the present Food and Drug Act, but it is obvious that the proponents of the new measure believe that to accomplish these objects more effectively certain additional powers should be created under the law, particularly (1) the powers given the Secretary of Agriculture in section 303 to determine definitions of standards of identity and quality and (2) the provisions relating to false advertisement.

Each of these two new provisions appearing in the new measure represent substantial and important broadening of the Federal power in this type of legislation and before being granted indiscriminately with reference to food, drugs, and cosmetics, the nature of these three industries, the public interest which are sought to be protected, and the motives and buying habits of the purchasing public in these three fields should be examined to make sure that legislative treatment which might be necessary to apply to one industry to protect the public interests is necessary for the same purposes in another industry.

It is to be noted that these two important extensions of power are apparently designed to strengthen and make more effective only the second of the two public interests to be accomplished, namely, the safeguarding of the public from fraud and deception, and that they have no relation to protection of public health. Are the underlying facts, therefore, in the three industries so similar as to require similar legislative treatment to make more effective the protection of this particular public interest? We do not believe so, and we urgently recommend that separate treatment be accorded food to avoid the danger of destroying greater public interests and value than that which is attempted to be made more secure. People purchase food in order to consume it and thereby to live and their selection and choice of food is largely based on flavor, taste, and other factors which vary among individual and various parts of the country. If, through the proper labeling, they are protected from adulteration of the food and from deception as to

what ingredients the food contains, their interests are thoroughly protected. They consume food three time daily and they are intimately familiar with all kinds of food products and their ingredients and their effect on their physical system. They do not purchase food with the idea in mind that it will accomplish a specific claimed purpose, nor do they rely on and expect a fixed standard of strength and quality of ingredients.

In the case of drugs, however, we find a totally different set of reasons governing the purchase of a drug, for people do not purchase a drug for its taste or flavor, nor do they purchase drugs continuously, nor are they in any way familiar with the nature and contents thereof. People purchase drugs in an effort at self-medication, so they must be able to rely on a definite strength of ingredient and they should not be deceived as to what the drug can accomplish therapeutically by false claims or opinions. In other words, there is far more necessity in order to protect this particular public interest for reliance on the part of the purchasing public on the statements made by the manufacturer concerning his product either on the label or by advertising and there is also much greater necessity for fixed standards of identity (since the purchaser of his own knowledge knows nothing of the strength of the ingredient) and hence there is some justification for extending the power of the Government to protect the public from fraud and deception. The same considerations generally apply to cosmetics, which are largely chemical combinations.

STANDARDS

Our chief specific objection to the bill is the power granted by section 303. This power is one which has nothing to do with the preservation and protection of public health or to the protection of the public from fraud and deception. If the food product is pure, is not misbranded, and if the advertisements relating thereto are not false, then the public should be left free to choose and buy the food product on the basis of its likes and dislikes and the manufacturer free to determine for himself the character and quality of his product. The purchasing public is very quick to find out which food products are of good quality and which are mediocre or of low quality, and if in doing so they are not given harmful products or are not deceived and misled by labeling or the advertising as to the nature of the products or the ingredients therein, they will have been fully protected. To grant such powers to any governmental body as are contained in section 303 (with the exception of provisions relating to fill of container) is merely to give government an arbitrary control over private business without any substantial relationship to the protection of any real public interest involved. Such a power goes far beyond the necessities of the case and in effect it gives the Secretary of Agriculture power to tell a food manufacturer who sells in interstate commerce just what sort of food he can manufacture, if the manufacturer wishes to continue to use the name which he has always used for the product.

For example, under the provisions of section 303 the Secretary of Agriculture, with the approval of the committees created by the bill could say to the baker, "If you market a bread product in interstate commerce called rye bread which you designate as rye bread, it must contain at least 35 percent rye flour; or if you market bread called cheese bread, it must contain a certain percentage of cheese; or if you market bread called raisin bread, it must contain a certain amount in weight of raisins. You cannot use these various names for various types of bread unless your product meets these definitions even though your product is pure and wholesome and has met consumer acceptance in your market for many years, simply because we say that according to our opinion this, and nothing else, is what the public should have when it buys rye bread or cheese bread or raisin bread." Such a dictatorial power over the initiative and freedom of the American business man engaged in the manufacture of food products is intolerable and cannot be supported on any ground other than a philosophy of government that it is the proper function of our Federal Government to take charge of and regulate every activity of private business in a spirit of paternalism, leaving the food manufacturer merely a servant, without initiative or freedom in one of the vital spheres of his activity, to carry out the whims and dictates of a government bureau. It will be said that the bill gives adequate protection in this respect by recourse to the courts for review of any regulations or definitions or rulings that might be made under this power. Why should the honest and legitimate food manufacturer be put to the burden and expense of correcting the exercise of such powers, and furthermore, what assurance is there that the courts can protect him from injustice in such cases when they are bound to give effect if possible to the declaration of policy of Congress in such a matter, assuming that the power is one that can be legally granted to the Secretary?

We feel that it is as impracticable and unwise to standardize the taste, likes, and dislikes of the consuming public. The result of such an attempt to define standards of quality and identity would be to bring all food makers down to a common denominator, and the legitimate commercial advantages that the trained and special food maker has over the inefficient and ignorant food maker would be lost.

While it may well be that in the case of drugs and cosmetics the preservation of the public interest involved necessitates the curtailment of the private interest of the manufacturer, it is very clear that as to food such is not the case and that such powers would not constitute regulation but would amount to management, control, and dictation, depriving the food manufacturer of his fundamental right to conduct his own business along customary lines.

FALSE ADVERTISEMENT

We urge the omission of the word "opinion" in the definition of advertisement as contained in section 2 (j). The present provision of the bill would greatly curtail advertising of food products since, due to the heavy penalties provided in the act, very few persons would be willing to risk a test of whether or not a given opinion was false or misleading. A manufacturer might well hesitate to state, for example, in this advertising that "in our opinion Blank's bread is the best bread on the market" for fear that it could be demonstrated in court that that this statement of his opinion was false and that some other bread was better. The determination of the question whether a given opinion is false or misleading is very difficult, and in the absence of a court declaration there would be a natural hesitancy on the part of the advertiser of food products to say much more about his food than its name and who manufactured it.

This, we believe, would definitely tend to cause a decrease in the consumption of farm products. Granted that such a result is not a certainty but is merely a probability or possibility, why should anyone, particularly the Department of Agriculture, wish to take the risk of such a result at a time when the most strenuous efforts are being made in all directions to close the gap between production and consumption of farm products? If such drastic provisions were necessary to protect the public health, or further to protect the public from fraud and deception by reason of false claims of specific results to be accomplished by use of the article, as in the case of drugs and cosmetics, it would perhaps be justifiable so to limit the legitimate efforts of the food manufacturer to increase the sale of his product.

ADMINISTRATIVE PROVISIONS

We further suggest that if the power to define standards of identity and quality is retained in the bill, that the following modifications be made to the general administrative provisions (ch. 7).

(*a*) In the selection of the committee on food standards to be set up under subsection (b) of section 703 we suggest that a panel of several representatives from each particular food industry be chosen and that when definitions for the foods manufactured by the baking industry, for example, are to be considered, the two food industry members contemplated by this section should be selected from those on the panel who are engaged in the baking industry in order that committees when functioning on questions of that industry, or any particular industry, may have the benefit of the knowledge of the two members familiar with its problems. Under the present arrangement it is quite possible that the committee contemplated by this subsection might, for example, in attempting to define products of the baking industry be composed entirely of members having no knowledge of its problems, since the two food industry members might well be a canner and a meat packer who would know no more about the baking industry than the representatives of the administration or the representatives from the public.

(*b*) We also suggest that in view of the important nature of the work to be done by this committee and of the time that will necessarily be required to do it properly, that provision be made for compensation of the members of such a committee for its services and reimbursement to it for its expenses; otherwise, we feel that the matters to be considered by such a committee would not be given the time, attention and careful consideration that they would certainly require.

——— ———,
President.

Senator CLARK. Mr. Jacobs.

STATEMENT OF WILLIAM P. JACOBS, EXECUTIVE MANAGER, INSTITUTE OF MEDICINE MANUFACTURERS, NEW YORK

Mr. JACOBS. My name is Will P. Jacobs, executive manager of the Institute of Medicine Manufacturers of 551 Fifth Avenue, New York, N. Y., an organization supported by 65 leading manufacturers of reputable proprietary remedies.

From the standpoint of public interest, as well as the interest of the press, radio, the advertising fraternity and reputable medicine manufacturers, there are a number of objections, as we see it, to the Copeland bill, S. 5.

Considering only the phases of the bill which have to do with drugs, we have prepared an analysis of the bill, which is just off the press, and is presented herewith in printed form, entitled "A Study of the Dangers of S. 5".

This study analyzes and classifies many of the dangers as we see them. We therefore ask that you accept the printed study along with the following brief discussion, which will be confined to the three principal dangers of the bill.

As we understand it, the order of the day is a presentation of constructive suggestions, along with objections; and as we are deeply interested in the passage of fair and constructive legislation regulating drugs, we will in this brief discussion of each of the three principal objections to the bill describe the objections, briefly outline our reasons therefor, and in each instance offer what we believe to be a constructive suggestion for the improvement of the defects.

The principal difficulties, as we see it, in the Copeland bill S. 5 are, as we see them—

First. The skeleton nature of the bill, which grants too much authority to the Secretary of Agriculture.

Second. The drastic provisions for seizures and injunctions in minor instances.

Third. The transfer of the function of regulation of advertising from the Federal Trade Commission.

Taking them in order as named:

SKELETON

The cause.—As we understand the bill, there are numerous provisions which grant too much authority to the Secretary of Agriculture. Eleven of these provisions are mentioned in the study which accompanies this presentation. As we see it, in practice he will, by this bill, virtually be clothed with authority not only to enforce the law, and in many instances to interpret the law, but in some instances to actually make law to cover the indefinite provisions.

The Effect.—If these many provisions, granting widespread authority to the Secretary of Agriculture, remain in the bill, and if the bill becomes a law, legitimate industry, as well as the fakers will, in many vital matters, be left largely at the mercy of the Secretary of Agriculture. He and his department will be authorized to prescribe rules, regulations, lists of diseases which cannot be advertised, privileges, exemptions, degrees of regulations, methods of application, nature and wording of advertising, examinations and investigations, rules of legal procedure, etc. So wide would be the latitude that a prejudiced employee of the Department of Agriculture might be able to seriously harass legitimate industry, and because of differences of opinion in minor matters seriously disrupt the orderly process of legitimate commerce. We believe that such provision is thoroughly out of harmony with a democracy and dangerous to the welfare not merely of legitimate industry but of the profession and public alike.

The Remedy.—It would take up too much of the committee's time to suggest a remedy for each of the provisions in the bill which grant the Secretary too much latitude. In general, we would urgently recommend that the committee seriously

consider the study of some of these provisions, and undertake, wherever at all feasible, to more definitely state the authority of the Secretary, in order that industry, the press, and the public alike may be more safely assured and more definitely advised as to the exact limits of the Secretary's authority. A more definite bill would be more desirable, as well as more practical and more fair.

Senator COPELAND. Just a moment. Is it not a fact that in this bill these regulations must be passed on first by a committee appointed by the President of the United States?

Mr. JACOBS. Yes, sir; that is correct, sir.

Senator COPELAND. So the power is not arbitrarily in the hands of the Secretary.

Mr. JACOBS. As I read the bill, Senator, the Secretary is not obligated, however, to follow other advice in the matter.

Senator COPELAND. I do not take it that way. Furthermore, I want to call your attention to the fact that in your bill you have got 8 such instances, and we have 15 such instances in ours, so you are at least half as bad as we are.

Mr. JACOBS. You are referring to the Mead bill, Senator?

Senator COPELAND. Yes.

Mr. JACOBS (reading):

SEIZURES

The cause.—Section 711 of the bill provides for seizures of any drug seemed adulterated or misbranded if the Department has probably cause to believe that the article is so adulterated as to be imminently dangerous to health, and jurisdiction of the court attaches upon such seizure.

Senator COPELAND. You will bear in mind, will you not, that this man, Mr. Dunn presented an amendment to section 710, institution of criminal proceedings, which was acceptable to the Department, that before reporting any violation of this act, there should first be an opportunity given to the manufacturer to appear before the Secretary and state his case, so that the manufacturer would not be taken immediately on the report of some inspector into court, he would have an opportunity to go before the Secretary and state his case first. So he has first that opportunity before any action is taken.

Mr. JACOBS. I think, Senator, that is a very constructive suggestion. Under those circumstances, with your permission, I will skip over the discussion of the matter of seizures and proceed to the last consideration in my presentation. [Reading:]

AUTHORITY FOR CONTROL OF ADVERTISING

The cause.—It is most unfortunate that the Copeland bill very definitely transfers the authority for the control and regulation of advertising from the Federal Trade Commission to the Food and Drug Administration of the Department of Agriculture. In the first place, the act attempts to go beyond the control of quality of drug products, and the labeling and advertising pertaining thereto, and attempts to regulate as to the containers, trade-marks, and other matters which would amount to the unfair trade practices, (see several subdivisions, sec. 402), the authority in such matters being now properly under the jurisdiction of the Federal Trade Commission and the courts.

While S. 5 does not repeal the authority of the Federal Trade Commission, in practical application the bill will so widen the authorities of the Food and Drug Administration as to enable them to seriously duplicate, if not supersede the Federal Trade Commission in the control of advertising.

The effect.—The Federal Trade Commission and its special board of investigation have for years been effectually controlling advertising in spite of its legal limitations in having to prove unfair competition. If, as it clearly indicated in the Copeland bill, it is intended that the Federal Trade Commission shall be

relieved of the responsibility of the control of advertising of food, drugs and cosmetics, then indeed the bill becomes a serious one for legitimate advertisers. The tendency of label regulations of the Food and Drug Administration has for years been toward the elimination of most therapeutic claims for medicines. The same tendency and policy followed in the conduct of advertising would not only render advertising ineffective commercially, but it would render it also more difficult to understand for the public.

Hard and fast regulations, rigid rules, without the consideration of the ordinary well-understood salesmen's puffery, would yield a serious blow to advertising. The uncertainty resulting from a dogmatic attitude toward advertising on the part of the Department would greatly curb advertising volume, not only fake advertising, but also truthful and legitimate advertising. The Federal Trade Commission, a commercial body, has well understood the functions of advertising, and is in a far better position, from the standpoint of experience in the field, to continue the regulation of this function.

The Federal Trade Commission is empowered by the Federal Trade Commission Act to prevent unfair methods of competition in interstate commerce. The courts have held false advertising to be such an unfair method. The Commission has effectively functioned in this field for 20 years. A multitude of guide posts for business have been established by the Commission, many of which have been approved by the courts. A long line of judicial precedents have been established and should not be destroyed. Foods, drugs, or cosmetics that are dangerous to health, or injurious to users, should be removed from all channels of commerce and placed beyond the reach of the buyers who do not know the dangers. The Secretary of Agriculture, Public Health Service, or some other qualified governmental agency should be given all necessary authority to protect the public from dangerous drugs. The Copeland bill apparently does this, but the bill also goes much further, and authorizes the Secretary of Agriculture to duplicate the work of the Federal Trade Commission. The Secretary of Agriculture should be given ample authority to protect the public health, but not authorized to duplicate the work of the Federal Trade Commission in protecting the public purse. The interest of public health and the interest of industry and commerce will not be served by duplication of authority of governmental agencies, and will not be served by the transfer of authority from an agency which has already proven its efficiency full well, to one which has for years jealously sought such authority, but which has never proven either its ability to properly execute such authority or to have a true conception of the commercial functions of advertising.

Advertising should be regulated, and it is. It should, however, remain under the control of the Federal Trade Commission, where it now is efficiently and fairly handled. Advertising is a commercial function. The Federal Trade Commission is a commercial body. Advertising is not an agricultural function. An agricultural product, after being processed, passes from the field of agriculture to the field of industry and commerce, and should in the main cease to be of concern to the Department of Agriculture. However, whether or not the Department of Agriculture is thoroughly capable of more efficiently regulating advertising than the Federal Trade Commission, it has never yet been explained why it is necessary to leave the regulation of all other types of advertising in the hands of the Federal Trade Commission, and specifically assign the function of control of advertising of food, drugs, and cosmetics to a separate department. A very distinct line of demarcation should be established by your committee, in our judgment, between the protection of public health in items which are perilously dangerous, and which should by all means be not suppressed but annihilated, and the protection of the public pocketbook, which is essentially a commercial or trade function.

The remedy.—For practical purposes we suggest amending the Copeland bill by adding to section 708 a clause as follows: "The Secretary shall report to the Federal Trade Commission all cases of false advertising intended to promote the sale of food, drugs, or cosmetics that are not perilously dangerous to health, or injurious to users, that may come to his knowledge, and submit therewith all evidence he may have, together with the scientific opinions of his department."

Such a provision would leave the regulation of advertising in the hands of the Federal Trade Commission, where it rightfully belongs. The Food and Drug Administration would have full right to suppress the manufacture of drug products which are perilously dangerous to health. If such perilously dangerous products are suppressed, there would be no need of the authority to control the advertising, for they would not only no longer be advertised, but would not even be manufactured.

Thus we present to you the three principal dangers of the bill, as we see them. In conclusion we would like to register our extreme protest against any legislative step which would undo the great constructive good which has been done by the present Food and Drugs Act. It has been amended, frequently interpreted by the courts; and coordinating and accompanying legislation passed by the several State legislatures.

This process required many years of effort, and many millions of dollars of expenditure by the Government and industry alike. It would be extremely unfortunate to undo all of this fine record, and to have to go again through the passage of a brand new food and drug law, and through such a long, tedious, expensive and serious process of further court interpretations, amendments, and legislative coordination. Such a process, it seems to us, is fully unjustified by the circumstances.

If the Copeland bill is revised to make it practical and fair, it still should be offered as an amendment to the Food and Drugs Act of 1906.

Respectfully submitted.

INSTITUTE OF MEDICINE MANUFACTURERS,
By WM. P. JACOBS, *Executive Manager.*

Senator CLARK. Mr. Hardy. Mr. Jordan.

STATEMENT OF STROUD JORDAN, NATIONAL CONFECTIONERS ASSOCIATION OF THE UNITED STATES

Mr. JORDAN. Mr. Chairman, the original S. 5, as submitted by Senator Copeland, met with the unqualified approval of many confectioners, and I might say has the undivided support of the committee, having to do with the food legislation, as well as myself personally.

In looking over Committee Print No. 3, however, we find two changes which do not materially assist in the enforcement of the act, but as the same time may lead to a lot of trouble.

Senator COPELAND. What is the reference?

Mr. JORDAN. I refer first to page 8, paragraph (i), starting with line 13. All of this has been deleted as it appeared in the original bill, except for the words "That, to the extent that compliance with the requirements of subdivision (2) of this paragraph is impracticable exemptions shall be established by regulations promulgated by the Secretary."

In the first place, it is going to be a rather hard proposition for the Secretary to determine what is or is not impracticable. It is unthinkable that he would have sufficient knowledge of all manufacturing processes to be able to judge this. It will be argued, however, that the food standards committee will check standards. This, of course, will correct this evil, provided the standards are set early enough.

Also the provision at the end of this same paragraph, starting with line 20.

Senator COPELAND. Just a moment, Doctor. Is it your suggestion that the language deleted be restored to the bill?

Mr. JORDAN. It is my suggestion that paragraph (i) as it appeared in the original draft S. 5 be restored in its entirety to Committee Print No. 3. That, I believe, will cover it, without any further remark, including the proviso whereby the materials may be filed with the Secretary. The reason for asking for this restoration, and particularly the last, is that presumably the food standards committee are going to set standards, and if they do, those products that are standardized will automatically be out of the class referred to in paragraph (i). If that is the case, then the only effect that would

be had in striking out this particular proviso is that it would make the manufacturers change labels for the period of time necessary for the food standards committee to formulate regulations which shall be recommended to the Secretary.

Senator COPELAND. When does this bill take effect?

Mr. JORDAN. One year after date, I believe.

Senator COPELAND. Would not that give the committee time to establish those standards?

Mr. JORDAN. I might answer that in another way, Senator, by saying that for more than 2 years the food standards committee of the National Confectioners Association have been trying to arrive at standards for confections. At the present time we have a tentative draft. If we, being familiar with confections, have required more than 2 years, I do not know just how long it might require a food standards committee, containing two members from the food processing and manufacturing industry, to arrive at standards.

Senator COPELAND. We were impressed with the idea of having a panel, so when an industry was affected, two of that industry might sit with the committee.

Mr. JORDAN. I think that is an excellent idea, because they could furnish information that would be impossible to get in any other manner.

Passing on for a moment from there to the second and last, I refer particularly to paragraph (k), line 10, page 9. It reads,

If it bears or contains any artificial flavor, artificial color, or chemical preservative and it fails to bear a label stating that fact.

I offer as an amendment the following wording:

If it bears or contains any chemical preservative, or if it be a natural product, or made in imitation of a natural product and contains artificial flavor or artificial color and it fails to bear a label stating that fact.

Senator COPELAND. That will show in the record, will it not, that suggested change?

Mr. JORDAN. Yes. The reason I asked for that can be explained very simply and very briefly. Deception or the coloring of inferior articles is already covered. Presumably all colors to be used will be harmless, because provision has been made whereby they must be certified. Since this is the case, they cannot be harmful. There can be no deception unless it is used to simulate some product other than it is. For example, should I take a cream fondant and add to it a brown color similar to chocolate, and add some artificial flavor to it, and then by inference, or by word of mouth, or by actual advertising, offer that for sale as chocolate, that would certainly be fraudulent. However, if I make a sugar cream which is not colored, which has no flavor, it has a taste which is sweet, any color, regardless of whether it was natural, or any flavor, regardless of whether it has been a naturally derived flavor, if added would become an artificial flavor or color, because sugar creams of themselves have no color or flavor.

It was brought out by the two who preceded me that the use of color, and flavors, for instance in baking, for icing, and also in ice cream, is a permitted practise under the present law without making any statement of this fact. Candy, for instance, hard candy, composed of sugar of one sort or another, corn sirup, malt sirup, dextrose, or any of the usual sugars, except for a sweet taste, has no flavor unless something is added.

It is submitted that the addition of color which is harmless, which enhances the appeal of a product, a color which the consuming public has been accustomed to obtaining, is in no way fraudulent, nor does it endanger the public health.

If, on the contrary, this paragraph (k) is enforced as it stands, it will mean the changing of the labels on all products which today carry artificial colors or flavors and which are not required to make such statement, and I do not believe anything would be gained by it.

In concluding, therefore, we recommend again that paragraph (i) be replaced by the paragraph in original S. 5, and that section (k), page 9, be amended to read as has been suggested. I thank you.

Senator CLARK. Mr. Parlin.

STATEMENT OF CHARLES COOLIDGE PARLIN, NATIONAL PUBLISHERS ASSOCIATION

Mr. PARLIN. My name is Charles Coolidge Parlin. I appear on behalf of the National Publishers Association.

I have the honor to represent the National Publishers Association, which consists of approximately 227 magazines, trade papers and agricultural, religious and scientific publications, with an aggregate average net circulation of approximately 50,000,000. It includes all magazines which are leading factors from the standpoint of advertising revenue.

Our publications depend upon the confidence of our readers, and because of the understanding interest which exists between our readers and our publications, we yield rank to no one in claiming a right to speak in the interest of American consumers.

At the original hearing on S. 1944 (the so-called "Tugwell bill") on December 8, 1933, the National Publishers Association voiced their hearty approval of legislation to protect health and also voiced their hearty approval of legislation to prevent false advertising of food, drugs, and cosmetics.

We did, however, point out to the subcommittee various provisions of that bill, such as Government grading of foods enforced by so-called "voluntary" inspection, which had nothing to do with protecting health, and which we felt would work out to the disadvantage both of the consuming public, of the farmer, and of the food and publishing industries.

At the hearing before the full committee on the revised Senate bill 2800, February 27, 1934, the National Publishers Association presented a resolution which read:

> We believe that those provisions of S. 2800 on which we feel competent to express an opinion are satisfactory. We therefore recommend to the members of the National Publishers Association not to oppose the passage of Copeland bill S. 2800.
>
> On provisions which manufacturers are more competent than we to express an opinion, we recommend full consideration for amendments which manufacturers may offer.
>
> If any amendment materially changing the meaning of provisions which have special interests to publishers be adopted, we reserve the right to alter this recommendation.

We appear today to voice again our approval of legislation to protect health and to prevent false advertising of foods, drugs, and cosmetics, and to express a hope that suitable legislation may be enacted at this session of Congress.

We believe that much progress has been made in the production of a bill which will adequately protect the public and at the same time will be a practical measure.

The National Publishers Association does not suggest any change in the provisions of S. 5 as it now stands. We are, however, conscious that there are mooted questions on a number of points and that provisions and phrasing differing from S. 5 have been presented to Congress in S. 580, introduced by Mr. McCarran, and H. R. 3972 introduced by Mr. Mead.

As to the relative merits of varying provisions and phrasing, we express no opinion, but wish to say that we shall be pleased if the committee will report out favorably S. 5, either as it now stands or with substitutions from S. 580 and/or H. R. 3972.

We would, however, be unanimously and strongly opposed to the introduction into S. 5 of any of the provisions of the original Tugwell bill, to which we voiced objection at the original hearing on December 8, 1933.

The National Publishers Association asks for fair consideration of the merits of conflicting opinions on mooted points and respectfully urges prompt action in reporting S. 5 for passage as it now stands or with whatever substitutions from S. 580 and/or H. R. 3972 you may think desirable.

Senator CLARK. The committee will adjourn until 1:45.

(Whereupon at the hour of 12:30 p. m., the committee adjourned until 1:45 p. m. of the same day.)

AFTER RECESS

The committee resumed the hearing at 1:50 p. m.

Chairman CLARK. The committee will come to order.

STATEMENT OF W. J. SCHIEFFELIN, JR., CHAIRMAN OF LEGISLATIVE COMMITTEE OF THE NATIONAL WHOLESALE DRUGGISTS ASSOCIATION

Mr. SCHIEFFELIN. Mr. Chairman and Senator Copeland, I represent an asssociation which has 215 active wholesale drug members and 326 associate manufacturing members. The wholesale active members handle 75 percent of the wholesale drug and medicine distribution of this country, an annual volume of over $300,000,000 of business. That association is now in its sixty-first year, one of the oldest trade associations in the country, and during that period it has consistently helped public welfare.

Before I come to the four specific recommendations that our association wishes to make, may I for a moment recall that in 1906 my father was a friend of Dr. Wiley and worked with him for the passage of the present Food and Drugs Act and had a part in obtaining support of the wholesale drug industry for the present law.

We are in full accord with the modernizing of this law, and believe that the inclusion of cosmetics and medical appliances is proper and necessary.

After careful study of the numerous proposed bills and revisions, leaders of our association feel that the National Wholesale Druggists' Association should not take a position for or against any one of the

It is submitted that the addition of color which is harmless, which enhances the appeal of a product, a color which the consuming public has been accustomed to obtaining, is in no way fraudulent, nor does it endanger the public health.

If, on the contrary, this paragraph (k) is enforced as it stands, it will mean the changing of the labels on all products which today carry artificial colors or flavors and which are not required to make such statement, and I do not believe anything would be gained by it.

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>
> If any amendment materially changing the meaning of provisions which have special interests to publishers be adopted, we reserve the right to alter this recommendation.

We appear today to voice again our approval of legislation to protect health and to prevent false advertising of foods, drugs, and cosmetics, and to express a hope that suitable legislation may be enacted at this session of Congress.

We believe that much progress has been made in the production of a bill which will adequately protect the public and at the same time will be a practical measure.

The National Publishers Association does not suggest any change in the provisions of S. 5 as it now stands. We are, however, conscious that there are mooted questions on a number of points and that provisions and phrasing differing from S. 5 have been presented to Congress in S. 580, introduced by Mr. McCarran, and H. R. 3972 introduced by Mr. Mead.

As to the relative merits of varying provisions and phrasing, we express no opinion, but wish to say that we shall be pleased if the committee will report out favorably S. 5, either as it now stands or with substitutions from S. 580 and/or H. R. 3972.

We would, however, be unanimously and strongly opposed to the introduction into S. 5 of any of the provisions of the original Tugwell bill, to which we voiced objection at the original hearing on December 8, 1933.

The National Publishers Association asks for fair consideration of the merits of conflicting opinions on mooted points and respectfully urges prompt action in reporting S. 5 for passage as it now stands or with whatever substitutions from S. 580 and/or H. R. 3972 you may think desirable.

Senator CLARK. The committee will adjourn until 1:45.

(Whereupon at the hour of 12:30 p. m., the committee adjourned until 1:45 p. m. of the same day.)

AFTER RECESS

The committee resumed the hearing at 1:50 p. m.

Chairman CLARK. The committee will come to order.

STATEMENT OF W. J. SCHIEFFELIN, JR., CHAIRMAN OF LEGISLATIVE COMMITTEE OF THE NATIONAL WHOLESALE DRUGGISTS ASSOCIATION

Mr. SCHIEFFELIN. Mr. Chairman and Senator Copeland, I represent an asssociation which has 215 active wholesale drug members and 326 associate manufacturing members. The wholesale active members handle 75 percent of the wholesale drug and medicine distribution of this country, an annual volume of over $300,000,000 of business. That association is now in its sixty-first year, one of the oldest trade associations in the country, and during that period it has consistently helped public welfare.

Before I come to the four specific recommendations that our association wishes to make, may I for a moment recall that in 1906 my father was a friend of Dr. Wiley and worked with him for the passage of the present Food and Drugs Act and had a part in obtaining support of the wholesale drug industry for the present law.

We are in full accord with the modernizing of this law, and believe that the inclusion of cosmetics and medical appliances is proper and necessary.

After careful study of the numerous proposed bills and revisions, leaders of our association feel that the National Wholesale Druggists' Association should not take a position for or against any one of the

three bills now pending before Congress, but should take a definitely affirmative stand on a number of important fundamentals.

The National Wholesale Druggists' Association is prepared to support and work aggressively for the enactment at this session of a revised bill for the proper protection of the public. We believe this can be accomplished without undue hardship on legitimate industry by the inclusion of the four following fundamental principles:

First. Because of present harmonized State laws and valuable decisions of Federal and State courts, we believe that additions and amendments to the present law are preferable to an entirely new law.

Second. We believe that multiple seizures should be imposed upon the industry for adulteration only; or in the case of serious misbranding only on court order where necessary to protect the public. (Adulteration is usually subject to actual determination. Misbranding on the other hand is often a matter of opinion.) In other cases single seizures alone should be authorized.

Third. We believe that the most far-reaching and effective protection to the public against false advertising should be obtained through the procedure of (A) Federal Trade Commission proceedings, and (B) court injunctions. The machinery is already set up for this method. Experienced and well qualified men are now actually engaged in this work and have been for several years. This procedure would not call for materially increased appropriations.

Mr. Chairman, may I take a moment to explain the reasons that led us to this recommendation. I think, this morning, certain facts in the testimony were not clearly brought before this hearing. Various speakers mentioned the transferring or taking from the Department of Agriculture of control over advertising.

As we understand it, the Federal Trade Commission has now certain limited control over advertising, and far from taking something from the Department of Agriculture, as we understand the proposal in S. 5, it is to add a new department to the Department of Agriculture and take away from a coordinate department something that it is already set up to perform.

It seemed to us that an existing experienced government organization should be able to handle as well if not better than a brand new one, proper control of advertising and at a smaller increased cost to the hard-pressed taxpayers.

Fourth. We believe that so far as possible all obligations and prohibitions affecting control of matters involving public health and welfare should be specifically set forth in the law and not left to departmental regulations. Minor regulations affecting administrative procedure must, of course, be left to the administration as in the present law.

If these four principles are embodied in a revised bill, together with minor points on which the pending bills are not far apart, our association will actively aid in its prompt enactment. Such a bill should be passed at this session. Not only would it relieve both Congress and the drug industry of the costly and time-consuming uncertainty of the past 2 years, but primarily Congress would be properly performing its function of safeguarding and protecting the public health.

Senator CLARK. Mr. Benson.

STATEMENT OF JOHN BENSON

Mr. BENSON. As head of the American Association of Advertising Agencies, Mr. Chairman, I represent the national body of those who practice professionally the business of advertising, they are deeply interested in the advertising provisions of this bill, and I am authorized to deal only with those provisions in appearing before your committee.

We feel that legislation is needed to protect the consumer against injury to public health or practicing deceit on the purchasing public, and we would like to see a bill passed that protects sound advertising against being undermined by dishonest advertising in the field of food, drugs, and cosmetics and will enable its purposes to be effectively enforced. Of course, we also want a bill that will not handicap or interfere with legitimate business or sound advertising. That must make an emotional appeal to the public. It is very different from labels which are a factual statement of ingredients and uses, whereas advertising is a persuasive appeal to the public or to the consumer to induce the purchasing of goods, and we have to use emotional and imaginative appeals that cannot be literally construed, and do not deceive or harm the consumer; so it is important, we believe, in the definition of false advertising to have it clear and unmistakable, and proper leeway given advertising to be persuasive in appealing to the public; otherwise it is ineffective. It should also be borne in mind that this is a penal law.

The advertising provisions have been practically all clarified in conference with Senator Copeland. He has been very fair-minded and practical-minded about the needs of advertising in this bill, and we appreciate that very much.

There is one point in relation to false advertising that I would like to clarify here, if I may. The present section 601A, page 23, reads:

> An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any particular relevant to the purposes of this act regarding such food, drug, or cosmetic. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion.

We would like to suggest a more definitive description of false advertising as far as the purpose of the act is concerned, and we would suggest this phraseology:

> An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any respect relevant to safeguarding public health and/or practicing deceit upon the purchasing public regarding such food, drug, or cosmetic.

That is for the first sentence of this section.

For the second, I would like to endorse the suggestion of Mr. Dunn which he made this morning, in the phraseology:

> Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular of such representation it is not supported—

instead of "sustained"—

> by demonstrable scientific facts or substantial and reliable medical opinion.

Because we feel the word "supported" is adequate when you take the rest of the sentence into account. We think that sometimes it

might be impossible to obtain such unanimity of medical or scientific opinion as to "sustain" a claim, which might be reasonably "supported."

We would also like to have inserted the following paragraph in further definition of false advertising:

When construing and enforcing this provision, reasonable allowance, consistent with the purposes of the act, shall be made for harmless trade claims recognized by and under the common law.

We believe that this allowance should be granted advertising in view of its right to appeal to the emotions and to express enthusiasm for a product and its uses, along lines which do not either harm or deceive the consumer. If it is not feasible to have this paragraph inserted in the bill itself, we understand that the idea of it will be stated in the letter of transmission of the bill to the Senate, indicating legislative intent, in the following words:

Harmless trade puffery is to be permitted.

Mr. Dunn this morning suggested a change in the title for the purposes of the act to read simply "for the purposes of safeguarding the public health and preventing deceit upon the purchasing public," and if that should stand I think the present definition of false advertising would be adequate to our needs, but if it does not stand, then I would like to suggest a change of phraseology so that there will be no ambiguity as to what constitutes the offense of false advertising.

There is one other point that I would like to call your attention to, and that is section 401 A–1 on page 13:

A drug shall be deemed to be adulterated if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.

I can see the argument of the Department for using the word "adulterated" there because of the danger to health, but it seems to us a rather dangerous precedent to connect advertising or anything that is mistaken in advertising, whether it is in a prescription or a definition, with adulterated food, since it is naturally by its very nature an act of misbranding. Even if there is no essential difference in the penalties now imposed by the bill for adulteration and for misbranding, there might be something inserted in the bill later on which would make a difference, and we feel that advertising should always be connected with misbranding and cannot logically be related to adulteration.

Those, gentlemen, are the only objections we have today to the advertising provisions proper; that is, the definition of advertising, of false advertising, and the liability of advertising agencies and publishers, or rather the inexemption from liability.

As far as the question of jurisdiction is concerned in dealing with advertising abuses covered by this bill, whether to be vested in the Federal Trade Commission or in the Department of Agriculture we are taking no position at this time.

We are very anxious to have such a bill passed at the earliest possible moment as I described in the beginning of my remarks. We think it is needed both by the consumer and by the advertising business.

Senator CLARK. Dr. Jordan.

STATEMENT OF C. B. JORDAN, REPRESENTING THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

Mr. JORDAN. Mr. Chairman, I represent the American Association of Colleges of Pharmacy. This association has a membership of 53 of the 60-odd colleges of pharmacy in the United States. Therefore, we are primarily responsible for the education of the pharmacist who will operate under this bill. Not one member of our group is an attorney and we cannot employ attorneys, therefore I wish to make a general statement of the position of our association, if I may.

Here is the position of the association on the question especially of drug and cosmetic legislation. First, to broaden the definition of the word "drug" to include all devices, substances, and preparations intended for the treatment or prevention of disease in man and other animals, and all devices, substances, and preparations, other than food, intended to affect the structure or any function of the body.

Senator CLARK. Do you include in that such a thing as a shoulder brace or a purely mechanical device?

Mr. JORDAN. It is intended to affect the structure or any function of the body.

Senator CLARK. A shoulder brace might be intended to cause a man to throw back his shoulders more or breathe more deeply. You would not classify that as a drug.

Mr. JORDAN. I think this is practically the wording of the present bill.

Senator CLARK. I am just asking for the opinion of your association. Is it your opinion that that is classified as a drug?

Mr. JORDAN. No, sir; unless it is intended to affect the structure or any function of the body.

Senator COPELAND. Are you seeking to change the wording on page 2 of subparagraph (b)?

Mr. JORDAN. No; I have some suggestions later to give, Senator Copeland, if I may be permitted to present these. I would like to have them in the record.

Senator CLARK. Go ahead. I was just struck with the proposition of your calling a purely mechanical device a drug. I am not presently considering the question whether it might not be appropriate to consider it within the purview of an act as a drug, but it seemed to me to be a remarkable thing to include a purely mechanical device here as a drug.

Mr. JORDAN. Will you permit me to read the second definition?

Senator CLARK. Yes.

Mr. JORDAN. Second, to bring within its purview cosmetics and the advertisement of same, the word "cosmetics" to be defined to include all substances and preparations, except mechanical devices and unmedicated soaps, intended for cleansing, altering the appearance, or promoting the attractiveness of the person.

If I am not mistaken, the bill does include such things as you include as cosmetics.

Senator CLARK. I did not mention anything as cosmetics.

Mr. JORDAN. You have the same situation, and we are trying to eliminate it in cosmetics. I think it is better in drugs than cosmetics.

Senator CLARK. You make one distinction in one paragraph and another in another.

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Mr. JORDAN. Third, to require the manufacturer, packer, distributer, or other seller of drugs and medicines to state on the label his name and business address.

Fourth, to provide for the preparation by the Federal Government of an official list of such drugs as may be held at present to be habit-forming.

Fifth, to require in the case of habit-forming drugs and preparations in which such drugs are contained, a statement on the label giving the name or names of such drugs and carrying the warning, "may be habit-forming", except when such drugs and preparations are dispensed on prescriptions.

Sixth, to require in the case of all mixed drug products not listed in either of the official compendiums (the United States Pharmacopœia and the National Formulary) that the name and the quantity or proportion of each active ingredient be stated on the label unless such information has been filed with the Secretary of Agriculture.

Seventh, to provide for Government control over the sale and distribution of such drugs and medicinal preparations as cannot be adequately controlled by gross inspection by chemical or biological examination of the finished product. It is recommended that such control be effected by the issuance of special permits or by means of a system of licensing.

Eighth, to require each importer, manufacturer, and jobber engaged in interstate commerce in drugs and medicinal preparations to register with the Government his name, place of business, and the character of the business in which he is engaged or proposes to engage; such registration be granted only on evidence showing adequacy of plant, proper sanitary conditions, equipment and personnel sufficient for the business stated.

Ninth, to restrict the advertisement of any drug or medicinal preparation, regardless of the medium used for exhibiting or disseminating such advertisement, to the statement of facts with respect to any and all claims made for curative or palliative properties or value in the treatment or prevention of disease.

Tenth, to prohibit the advertisement by any means whatsoever of any drug or medicine as a treatment or cure for any of the following diseases or conditions: Blindness, Bright's disease, cancer, cataract, diabetes, epilepsy, locomotor ataxia, lupus, meningitis, paralysis, poliomyelitis, tuberculosis, tumor, and such other diseases as may be designated by the proper Federal authority.

Senator CLARK. Why not say such diseases as might be designated, then?

Mr. JORDAN. Perhaps that would answer it.

Senator CLARK. What was the reason for setting out a list of five or six and then saying "and such others as may be specified", or saying that the Secretary of Agriculture may designate any that he pleases?

Mr. JORDAN. I am glad you asked that question. The list I read has been prepared by the Minister of Public Health of England after careful study of such diseases as should not be treated by drugs without physicians' advice. That accounts for this list.

Senator CLARK. I am not disputing the validity of that list, but it does seem to me that if you specified certain diseases and then, say, that the Secretary of Agriculture has authority to put in any others that he pleases, you might as well say in the first instance that the Secretary of Agriculture has the absolute discretion to specify any diseases that he pleases. That is what it amounts to.

Mr. JORDAN. Perhaps you are right. We wanted to be sure that these diseases would be protected; that they should not advertise drugs for the treatment of these diseases.

Eleventh, to place the responsibility for the advertising of drugs and medicinal preparations on the individual or firm issuing it, unless such individual or firm furnishes a guaranty for the truthfulness of the advertising claims made, and the guarantor is amenable to the law, in which case the guarantor shall be held responsible.

Twelfth, to provide for the cooperation between Federal and State Governments in the enforcement of the food, drug, and cosmetic laws in their respective jurisdictions.

Our only interest in this bill is from a public health standpoint. We have no financial interest whatever, and our first, last, and only interest is that.

I would like to suggest some changes which have been embodied in this general statement.

On page 2, paragraph (c), line 17, add after the word "preparations" the expression "except mechanical devices and unmedicated soaps", so that it will read:

> (c) The term "cosmetic" includes all substances and preparations, except mechanical devices and unmedicated soaps, intended for cleaning or altering the appearances of or promoting the attractiveness of the person.

As it reads, I suppose obesity belts and other things like that could be included.

Second. Page 15, paragraph (c), line 2, add after the word "and" the figure "1", and in line 4——

Senator CLARK (interrupting). I do not think we are using the same print as you are, Doctor. What page is that?

Mr. JORDAN. Page 15.

Senator CLARK. Are you referring to the bottom of the page? There is a section there at the top of page 15 and a section there at the bottom of page 15.

Mr. JORDAN. I had it at page 15, paragraph (c).

Senator CLARK. The first paragraph there at the top of page 15 in which line 2 is included is:

> If it is not subject to the provisions of paragraph (b) of this section and its identity or strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

Is that the section you have reference to?

Mr. JORDAN. May I be permitted to make my statement clear, and I will correct that for the minute?

Senator CLARK. Yes, you may proceed.

Mr. JORDAN. The point that we had is this. If its purity or quality cannot be adequately determined by gross inspection or by chemical or biological examination, then the manufacturer should have the permit from the Department for manufacture so that those drugs that cannot be controlled by gross inspection or by chemical or biological examination will be controlled at the source by permit for manufacture.

Therefore, on page 15, paragraph (c), line 2, add after "and", the figure "1" and in line 4 after the word "possess" add the following:

Or (2) if its purity or quality cannot be adequately determined by gross inspection or by chemical or biological examination and the manufacturer does not possess a permit from the Department for such manufacture.

On page 23, line 22, add after the word "advertisement" the words "disseminated through any medium whatsoever". It is a question of how that advertisement shall be disseminated.

And on page 24, add to the list of diseases these that I have mentioned that are not already mentioned: "Blindness, Bright's disease, cataracts, diabetes, epilepsy, locomotor ataxia, lupus, meningitis, paralysis, poliomyelitis, and tumor".

May I say that our association believes that we should have a full and direct revision or a new law, preferably a new law because we believe the public needs it.

In general we are in favor of Senate bill 5, committee print 3, as it stands. If there are other modifications to it, then we would like opportunity to consider them before we pass judgment.

I wish to say that we agree with the statement made by Mr. Dunn and others to the effect that the enforcement of the advertising provisions of this act should rest with the Department rather than under the jurisdiction of the Federal Trade Commission.

Thank you.

Senator CLARK. Arthur Kallet.

STATEMENT OF ARTHUR KALLET, SECRETARY CONSUMERS' RESEARCH, REPRESENTING THE CONSUMERS' RESEARCH

Mr. KALLET. We are not in favor of the passage of S. 5. The bill apparently was drawn with the presumption that it is possible to protect both of the manufacturers and the consumers or the distributors and the consumers, and that is not possible. It is necessary to make a choice whether our prime interest is the protection of the business man in these industries or the protection of the public. As the bill is drawn it will protect the industries, and judging from the testimony that has been presented here and the reports in the trade press, and what has preceded these hearings, apparently the great emphasis has been on how to protect the industries. Our view is that the primary job of you men framing this legislation is to seek to protect the consumer. After that is done, and if it is possible, you can consider how to protect the honest business men, if you can find them.

Perhaps one of the most important additions that this bill would make to the existing food and drug law is in extending control over advertising. I want first therefore to talk a bit about the advertising section of S. 5. The section says, at page 23, section 601 (a):

An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any particular relevant to the purposes of this act regarding such food, drug, or cosmetic. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion.

I contend that that section as written will not protect the consumer. Let me bring up a few typical advertisements, and we must keep in mind in considering this section that the big advertisers particularly

have every opportunity and are able to hire some very clever men to write their advertising, and it has to be an extremely good advertising section that is going to prevent their finding some way of getting around it.

Here for example is an advertisement for Nujol.

This is a product that has been advertised constantly in the magazines and is advertised over the radio by Senator Copeland——

Senator CLARK (interrupting). Just a minute, Mr. Kallet. If you desire to make a statement having to do with the merits or demerits of this bill, the committee will be glad to hear you. The committee does not have any time to hear you indulge in personalities, or to have you attack a Member of the Senate or anybody else. If you desire to proceed, we will proceed with that in mind. [Applause.]

Mr. KALLET. Mr. Chairman, I am talking about the bill. If I mentioned Senator Copeland it is because of the fact that the hiring of important figures in public life is one of the means by which the advertisers defraud the public.

Senator CLARK. Mr. Kallet, I again admonish you that if you desire to proceed on the merits of this bill or the other bills involved in the same matter, the committee will be glad to hear you. The committee does not desire to hear you on any sort of personalities.

Mr. KALLET. I am not indulging and I have not indulged in any personalities, Mr. Chairman.

This advertisement for Nujol says such things as this:

A true story by a mother * * * imagine our encouragement and joy, a short time after my doctor put me on the Nujol treatment, when my health began to improve. In a few short weeks I looked and felt like a new person.

It says further:

Nothing we could add to Mrs. Ruhl's letter would make it any more convincing.

When your courts—after a case against such an advertisement as this is brought to court—to look for something that is false or misleading in any particular, they are going to have a hard time finding anything wrong with any particular of this advertisement.

A little later I want to tell what I propose for handling this, but I do not believe that advertisements of this type would be adequately covered by the bill as drawn.

Here is another one; our old friend Lydia Pinkham's Vegetable Compound.

My thirteenth child and seventh son. I am the mother of 13 children, 11 of whom are living. The youngster in the picture is my seventh son. I was weak and tired and suffered from nervous headaches. My sister recommended Lydia Pinkham's Vegetable Compound and it helps me a lot.

Happy mothers in 48 States recommend this medicine to their friends and neighbors.

Again you are going to have a hard time in a court that naturally will be friendly to the business interest and not to the consumer to protect the public under your bill as drawn.

If I may digress a moment, this business of the attitude of the courts is very important. After all any bill can be vitiated in the courts if the sympathies of the courts happen to lie in a particular direction. You may recall—I am sure Senator Copeland will recall—the case of the B. M. Internal Remedy. That was a horse medicine, and it was recommended for treatment, I think, of tuberculosis,

cancer, heart disease, and all sorts of ailments, and the court decided that that was not a case requiring drastic action. That is only a typical case.

In case after case, the courts very clearly show their bias in favor of the business man who is able to hire expensive lawyers and expert testimony.

Senator CLARK. The question of your opinions of the whole fiduciary structure of the United States are hardly within the scope of the jurisdiction of this commission.

Mr. KALLET. That is an extremely important particular, Mr. Chairman. You have to write a law so that it cannot be ruined by the courts.

Senator CLARK. Congress is not necessarily to proceed on your apparently very low opinion of the judiciary of the United States.

Mr. KALLET. Mr. Chairman, I do not expect Congress or this committee to pay any attention whatever to my opinions about anything. It has demonstrated it is not interested. [Applause.]

Senator CLARK. The Chair will admonish those people who are in the hearing room that they are here by the courtesy of the committee, and any demonstrations of approval or disapproval are strictly prohibited.

Mr. KALLET. My view is that it is important to place these things on the record on behalf of the consumers whom I represent.

I believe that the list of diseases for which any advertising should be banned should be greatly extended and not left to the discretion of the Secretary of Agriculture.

Here is an advertisement from a recent issue of a Los Angeles paper, an advertisement for diabetes. Here is another one for stomach ulcers from St. Paul.

Senator CLARK. It is your idea that the list should be made specific or that it should be left to the discretion of the Secretary of Agriculture?

Mr. KALLET. It should be made specific and cover a very large list of diseases, as was done in S. 1944.

Senator CLARK. It was also left more or less discretionary in that bill, wasn't it? It set out a very long list and then said "any such other diseases as the Secretary of Agriculture may from time to time determine should be added to the list."

Mr. KALLET. That is quite all right, providing we have a long and basic list to start with. Of course, you may consider it entirely irrelevant, but there again it is necessary to point out that the Secretary of Agriculture is subjected to pressures, and his actions frequently are not in favor of the consumer but in favor of business. That is one reason that I feel that that list should be long to start with.

There is one particular type of case that I think has got to be covered if our legislation is to be effective in the control of advertising. That is a case where there is no adulteration necessarily, or the product may be quite pure and in some circumstances quite wholesome and valuable, and yet which, by and large, can be very dangerous to the public and to individual consumers and to the public health. The best example of that type of product I know is bran.

Here is an advertisement of Kellogg's All-Bran, which is in the same class as the others that I mentioned, that is, that it would be very difficult to touch it under the law as it is written. Let me read you just briefly from the advertisement:

Enjoy more sunny days. Your moods, your actions, your very personality—all are influenced by the state of your health. Avoid common constipation due to insufficient "bulk" in meals. This ailment may cause headaches, loss of appetite and energy. It takes the color out of living.

Kellogg's All-Bran, a natural laxative food, furnishes you with the needed "bulk".

There is nothing there that you could put your finger on as being false or definitely misleading, and yet I contend that that product is doing a great deal of damage, and I want to read some statements from sources that I think you will consider authoritative to show that we have a product which is widely sold now and that would be continued to be sold under section 5, and yet which is very dangerous.

Here is a statement about bran from the United States Public Health Service that was made during the course of a radio broadcast sponsored by the United States Public Health Service. It says:

Whereas approximately a third of those eating bran are able to take it over an indefinite length of time without apparent harmful results, and even with temporary relief from a constipated condition—

I would like to call your attention to that, Mr. Chairman, that it says that only about a third of those who take bran can take it without apparent harmful results. They are not even sure that one-third of the consumers can eat this product safely, and yet it is advertised in every newspaper and magazine as a panacea. They stated further:

Yet by far the larger proportion of bran eaters develop a deep-seated irritation in one part or another of the intestinal tract. It is the opinion of excellent authorities that this irritation is often the fundamental condition leading to ulceration by producing localized areas of congestion and superficial loss of mucous membrane, thus creating a suitable field upon which subsequent disease may develop. In a majority of cases, after a short or long period, bran not only ceases to relieve constipation, but sets up localized spasm in different segments of the colon, thus developing a secondary constipation which at times is difficult to cure. Without being able to offer concrete proof, it is held that this condition may lead to the development of malignant diseases.

Which means cancer.

And yet your bill would not outlaw that advertising.

Here are some more statements. This one is from Dr. Morris Fishbein, editor of the Journal of the American Medical Association, on the effect of eating grossly improper foods:

Eating gross improper foods or chewing improperly, or taking food which in fiber is not digestible, or excess amounts of bran, may cause enough trouble to produce indigestion.

It is the opinion of competent authorities, as shown by a news item of a meeting on the subject of cancer held in Washington about a year ago, that quantities of rough food may be one of the causes for this malignant disease, and bran is one of the very roughest forms of food.

It is certainly apparent from this that Kellogg's bran or any other bran may cause not only indigestion and serious intestinal and stomach ailments, but actually may be responsible for cancer.

It seems to me you have a very important duty of writing the advertising section at least that will get rid of that kind of thing.

Let me read you just one more statement on the subject of bran, which comes from the Journal of the American Medical Association. There is particular interest attached to this statement:

Bran can be injurious in any type of constipation. * * * Patients with a weak digestion and a tendency to flatulence are like sooner or later to get into

trouble on any rough, bulky type of food. The frail bowels cannot handle it. Answers to a questionnaire indicated that the medical profession is anything but enthusiastic about bran. Most of the men who answered said that they no longer prescribed it and many warned their patients against its use on account of the indigestion it often produces. Dr. Alvarez reported the case of a woman who began the use of bran and in the succeeding 4 months went down hill until she was skin and bones. In her attempt to relieve the distress in the bowel she gave up one food after the other until she was living on little beside bran. It never occurred to her to drop that, because she had been lead to believe that it was a wonderful health food. * * * Manufacturers should warn buyers that not everyone can tolerate the substance and that its use should be stopped the minute it begins to produce indigestion, flatulence, and malnutrition.

Of course, your advertising section of this bill does not require any such branding, no matter how grave the danger is.

The particularly interesting thing about this last statement I read is in connection with the proviso in your bill that advertisements are not apparently to receive the same kind of scrutiny if they appear in scientific or medical publications. In the very same issue of the Journal of the American Medical Association in which this last statement about bran appears there is an advertisement for Kellogg's All-Bran, and of course the doctors read the advertising much more frequently than they read the scientific columns of their periodical. I certainly feel that advertising should be rigidly controlled wherever it appears.

There is another important phase to advertising control as set up in S. 5, and that is the section relating to scientific proof. It says:

Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion.

Mr. Chairman, I contend that this is not protection to the public, because every drug advertiser knows that it is perfectly possible to buy substantial medical opinion and buy demonstrable scientific facts.

Again let me cite cases.

The magazines all carry advertising for a product called "Vapex." Here is one advertisement which talks about recent tests by a medical research laboratory which tells about the great germ-killing power of Vapex and its great penetrating power. Vapex was tested by an apparently reputable medical laboratory, the Pease Laboratories in New York. If a manufacturer were out to get scientific tests to back up his claims in advertising and wanted to go to a laboratory that would be given credence in the courts, it is quite possible that he would go to the Pease Laboratories, and on the basis of those tests made by the laboratories, they claim this is a very fine antiseptic and germ killer, and yet after those claims were made the product was picked up by the Federal Food and Drug Administration; and, by the way, they claimed that this was a great war-time discovery. The Federal Food and Drug Administration when they analyzed it found that it consisted essentially of volatile oils such as menthol and lavender oil, with an alcohol content approximately 66 percent by volume, and water.

The notice of judgment relating to the seizure of Vapex says:

* * * the statement appearing in the circular, regarding the curative and therapeutic effect of the article, "laboratory tests have proved that the Vapex vapor kills the pathogenic bacteria present in the breathing passages" was false and fraudulent, since the article contained no ingredients or combination of ingredients capable of producing the effect claimed.

And yet they have the scientific proof, and it is scientific proof that the courts would in almost every case find acceptable.

Here is another kind of scientific proof. It is an advertisement for oranges and lemons, an advertisement bearing the signature of the California Fruit Growers Exchange. It refers to tests made by Dr. Milton Hanke, a member of Sprague Memorial Institute at the University of Chicago. They were very scientific tests, run over a period of 3½ years, and they purported to show that in a study of 341 children during that period, the consumption of a great deal of orange juice and lemon juice prevented dental caries.

Not only the layman, but the average physician reading a long book on this subject, the results of the tests, would conclude that here was the apotheosis of science, that it was absolutely all the scientific proof which anyone could require, and yet when the American Medical Association reviewed this book in the Journal of the American Medical Association, they found apparently that these researches had set out to prove a thesis and were able to prove it, but that from start to finish the test was absolutely unscientific, and yet any court would accept that kind of science.

There is another kind of science that the advertisers use, again which probably would be found quite acceptable to the courts. The current issue of the Journal of the American Medical Association contains an article by the Bureau of Investigation on the subject of questionnaires, and in this case it appears that a beer producer sent out a questionnaire to doctors with a long list of questions such as "Do you prescribe beer for nervousness?" "And do you consider beer good for this and that." "And do you consider it better than hard liquor?" And it appears also that if the doctor replied to this questionnaire he received free six bottles of beer.

Senator CLARK. That was a pretty cheap bribe, wasn't it?

Mr. KALLET. Cheap price. It appears that that same technique has been used very frequently by the advertisers and the doctors in order to get a carton of cigarettes or a wallet with their name in gold, or a fountain pen or something else, and have been quite willing to send in such questionnaires with their names signed to them, and I think you would not blame a court if it accepted an advertiser's statement because he was able to show that 10,000 doctors or 22,000 doctors agreed that his statements were correct.

In view of that, I do not feel that your proviso in the bill that advertising statements must be supported by substantial medical opinion or demonstrable scientific facts will protect the public.

As to what I propose, that is another story. I do not expect it to receive any serious consideration by this committee or by Congress, but I feel that it is absolutely the only way of protecting the public against false and fraudulent advertising, and that is to have all the advertising claims passed on in advance and approved in advance. There is absolutely no other way by which you can go out and catch the false advertisements and try to make charges against them stand up in the courts. If we are able to get together a group of scientists with no commercial connections, and I am not certain that it is possible, but if it were and it would be possible for them to pass on advertising before it appears, we might get some protection for the public. But under your bill——

Senator CLARK (interposing). Do not think of it as my bill. I had nothing to do with the preparation of the bill.

Mr. KALLET. I understand that, Mr. Chairman, and I apologize. As a matter of fact I understand you have expressed great disapproval of the bill, and, as a matter of fact, did not feel that any considerable additional protection to the public is necessary.

Senator CLARK. I will do my own expressing of opinion, and I resent your effort to put words in my mouth.

Mr. KALLET. I am sorry.

Another very important addition that we feel should be made to this bill or to any other bill intended to provide protection for the public and not for producers, is to require advance registration of all products which can affect health; issuing some sort of license in advance for a product, food, or drug, or cosmetic, which may affect health, so that no product which does not bear the Government's approval, which has not been registered with the Government, can go out into commerce.

Again let me talk in terms of cases. Here is a news item of a man who died as a result of using toothache drops that contained carbolic acid. He just went to a drug store and asked for something to relieve his toothache; they gave him a toothache drop and he used it and got large quantities of carbolic acid into his system and died.

I feel that it should be absolutely impossible for any such product to go into commerce. They should be weeded out in advance and not after they have killed some dozens of people, and if you think that that is not important because such things will be caught very quickly anyway, I would like to read a statement which I read in the hearing last year. It is a question which was addressed to the editor of the Drug and Cosmetics Industry by a manufacturer. He says:

> We have been marketing a cough remedy for 40 years and never got into trouble because of claims we made for it. But lately a lot of our stuff was picked up and condemned and we have been having considerable difficulty with the Department on this account. How can we find out what claims we can make?

They managed it for 40 years before any of this stuff was picked up. I do not feel that carbolic acid toothache drops or any other product should be marketed for 40 years or any other period of time if they are potentially dangerous to health. If the danger is very great they should be checked in advance, and if the danger is there they would not be allowed to go into commerce.

There is a great deal of advertising going on for various nose drops that contain or consist entirely of mineral oil. Just recently a researcher made the statement that probably mineral oil taken into the nose, dropped into the nose frequently, can cause spots on the lungs and might seriously injure the lungs. That may or may not be true. Certainly a statement like that, and findings like that have to be very carefully checked, yet is it not reasonable if our purpose is to protect consumers and not to protect the manufacturers, to require that when such a finding is made, at least a warning be given to consumers that this product may involve a serious hazard? If all products had to be registered in advance, or if their registration could be withdrawn if they were found to be dangerous, we have an easy way of handling that, but under our present law and under this bill, there is no way we could do it. Suppose that finding is substantiated; suppose it is found that this is injurious to the lungs, that injury can be caused by mineral oil, do you suppose that this product Mistol or other similar products are going to be taken off the market or that any warning is going to be given to consumers? Of course not. It is only if they can be threatened with the removal of their product from the market that such warning can be required, and they can be forced to protect the public.

Let me take another similar case. Perhaps it is even more important. Every household magazine contains a number of advertisements for breakfast cereals of various types. Here is an advertisement for example of Cream of Wheat, and it tells how valuable cereals are for children, how it builds them up, how good it is for their nerves, and so forth—all of which may be quite true, but for several years now there has been the opinion among researchers in this field that cereals may promote caries and may interfere with the development of the teeth, particularly if they are eaten in excess by children. May Mellanby in England in her book, Diet and the Teeth, makes the statement that the consumption of milk, eggs, cheese, animal and fish fats, vegetables should be greatly increased and the consumption of cereals diminished and for children abolished.

Naturally, there is no statement of that sort in this advertisement because it would cut their sale and interfere with their profits. Would this bill as written require any use of this scientific knowledge in advertising? Consumers would be permitted to go on taking this product in quantities just as though the scientific findings had never been made, and there again if the products were registered and a condition of the registration was that necessary and suitable warnings be given these consumers where a danger to health may exist, then we might have some degree of protection to the public.

Another case: There is a great advertising campaign going on now for a product called the Hexin. On billboards everywhere throughout the country you will find this product advertised as a modern remedy for something or other, and although there is nothing that any court would be able to put its finger on in particular that is false and misleading, this product contains amidopyrine. For a few years now it has been known that amidopyrine causes a very dangerous blood ailment, an ailment that has been responsible for a great many deaths, and no person is able to know whether or not he is susceptible to that in advance. There have been countless cases of this ailment in the hospitals and throughout the country, a great many deaths, and yet that product continues to be sold without any warning whatsoever, sold in drug stores generally as Pyramidon, and no warning is given, and the advertising of it goes on in the magazines and the billboards, and no warning is given that there is this danger. Such a product should have to be registered, a product that may be dangerous to health and where the danger is very clearly shown, as in this case, certainly this registration should be withdrawn and the product taken out of commerce. At the very best it should be permitted to be used only under a doctor's prescription. Certainly it has some useful qualities.

Perhaps one of the most important changes that needs to be made in this bill or in any other legislation that again would protect the consumers and not the producers is to take control out of the Department of Agriculture. There is a very unfortunate situation existing. The Department of Agriculture after all is not set up to protect the consumers—it is set up for the benefit of the farmer. Its aim primarily is to promote the welfare of the farmer and not of the consumer, and

yet a consumer-protective measure was placed under the control of this Department, and in cases where a conflict has arisen between the welfare of the consumer and the welfare of the producer, the producer has won, and the welfare of the consumer has been disregarded. It is for that reason that I feel that it is absolutely necessary to take such a measure as this out of the hands of what is essentially a producers' Department.

That is a very important thing, and I do not want to let it stand just on my mere statement. Let me cite a couple of cases:

In 1929 the then Secretary of Agriculture Hyde, in reference to Senator Capper's corn-sugar bill said:

> To permit the sale of corn sugar or artichoke sugar under the circumstances proposed by this bill would authorize the sale of such products as an ingredient of prepared foods where the purchaser would be definitely deceived and perhaps defrauded. Undoubtedly it would authorize the adulteration of cane syrup, maple syrup, and honey with corn sugar or corn-sugar syrup without notice to the consumer. Chemically, corn sugar and cane sugar are entirely different products by strikingly different characteristics showing markedly different behavior under different manufacturing conditions. The Food and Drugs Act was intended to prevent deception of the consumer. It is for Congress to say whether this principle shall be sacrificed in the interest of corn sugar or any other article of food. If established with respect to one commodity, it creates a precedent which could and undoubtedly would be pleaded for the extension of the same principle to other commodities. The multiplication of such amendments indefinitely would effectively repeal our Federal food law.

That was the statement made by the Secretary of the Agriculture Hyde in 1929, and yet in 1930 as the result of pressure from agricultural and other interests, Secretary Hyde reversed himself and permitted the sale of products containing corn sugar without any label declaration that the presence of that ingredient existed, and he justified it very nicely by saying:

> This ruling removes a discrimination against the use of corn sugar which has been too long permitted.

Despite the fact that previously he had said it would endanger our food and drug law if such discrimination were not made.

A still more important case and one which is extremely important today is that relating to insecticides. At present the Food and Drug Administration permits residues of arsenic and of lead to remain on fruit and vegetables. Let me read for you some of the statements of medical authorities on the subject of arsenic and lead in small quantities as they occur in such residues.

Here is a statement by J. C. Geiger, director of public health of San Francisco. He says:

> Spray residue poisoning in man occurs with some frequency. A recent instance in San Francisco is worthy of note.

And then he goes on to describe how one person there was very seriously poisoned by spray residues.

Here is a statement from Doctor Rabbinowitch, director of metabolism of the Montreal General Hospital, with relation to lead, one of the residues of insecticides. He said:

> Lead is known to produce the severest form of heart and kidney diseases. It is therefore not possible that exposure of the human body to small amounts of lead over periods of years may have the same effect as large quantities over shorter periods.

Dr. H. P. Cushing of the Children's Memorial Hospital, at a medical meeting in Montreal said:

> Lead poison in children often produces symptoms that are often taken for some other disease.

He told of children who appeared to have appendicitis, infantile paralysis, whooping cough, convulsions, and tuberculosis meningitis but whose symptoms really were caused by lead poisoning.

Here is an editorial from the Journal of the American Medical Association which says:

> * * * lead poisoning may stimulate every other disease of the central nervous system. Whether the minute quantities often present has any bearing whatever on obscure nervous symptoms, is an important question for serious consideration for the future.

And another editorial from the Journal of the——

Senator CLARK (interposing). Suppose you insert those editorials or statements, whatever one you desire, in the record. I have been very anxious to give you as much time as is necessary for the presentation of your case, and you have already consumed nearly twice as much time as any other witness. It is certainly not necessary for the purposes of the hearing to read a lot of interviews and statements having relatively nothing to do with the bill.

Mr. KALLET. I disagree with you strongly, Mr. Chairman; they have a great deal to do with the bill. As your bill reads it leaves control in the Department of Agriculture. I feel that the health of a great part of the population is jeopardized by the continued control of this legislation with the Department of Agriculture.

Senator CLARK. You are at perfect liberty to discuss the bill, but there are a great many other witnesses to be heard, and I do not care to have the time taken up by cumulative reading of extensive scientific opinions.

Mr. KALLET. It certainly relates to the bill, Mr. Chairman.

Senator CLARK. That is a matter of opinion. You are at perfect liberty to insert all of those opinions in the record that you desire, but the committee has something else to do besides to read a rehash of your book.

Mr. KALLET. None of this material appeared in my book, which I doubt that you read anyway; and it certainly is important to consumers generally if their health is being jeopardized by your failure to make an important change in this bill. All of this material bears on the subject.

Senator CLARK. You have permission to insert it in the record. But you do not have permission to take up the whole hearing by repetition of a similar line of testimony.

Mr. KALLET. Let me just read two very, very brief statements, Mr. Chairman, about small quantities of these insecticides, because they bear on the rulings of the Department of Agriculture.

Senator CLARK. All right; proceed.

Mr. KALLET. One is a statement by some of the foremost authorities in New York as to the latent effects of metals, that they attack more individuals than those with the chronic and acute symptoms.

And here is a statement of the relation of arsenic to public health from the New York State Journal of Medicine, July 15, 1929:

> Deaths from chronic arsenic poison have been noted 8 years after the exposure In our cases it is not uncommon to find clinical symptoms 2 to 6 years after the exposure.

And here is a statement by Mr. Crawford of the Department of Agriculture on food and drug administration and the technical problems in food and drug law enforcement:

> Where poisons in foods are found in minute quantities, the proof of their harmfulness may present most serious difficulties. Complications arise from the fact that traces of poison continuously consumed may manifest results only after a period of years; first evidence of poisoning from infinitessimally small doess of lead have appeared as long as a decade or more after the beginning of the exposure.

And yet, Mr. Chairman, despite this evidence, much of it from the technologists of the Food and Drug Administration of the Department of Agriculture, and as a result of pressure from agricultural interests, the Food and Drug Administrations has ruled that these poisons which, in the amount which remain on foods can cause grave injury to very large parts of the population, they have ruled that those residues may remain on the food.

Senator COPELAND. Will you let me have the editorial from the American Medical Association Journal?

Mr. KALLET. Certainly.

Only a few weeks ago, Secretary Wallace sent out a statement on the subject of residues in which he again reiterated that these residues would be permitted to remain on fruits and vegetables and he said this, that unquestionably today most of the fruit offered to the public is entirely safe. That is contrary to the statements of his own technologists.

This callous attitude toward the public, Mr. Chairman, of Secretary Wallace and of the other members of the Department of Agriculture, Mr. Tugwell, and even the President who was cognizant of these things, is jeopardizing the lives of a very large part of the population. They are doing very grave damage. Apparently the fact that it is necessary to producers is sufficient for them.

The courts, as you know, when they consider such legislation as this, look into what the framers of the legislation had in mind. When Senator Copeland sent a report on his last bill to Congress at the last session he said:

> In promulgating such regulations, this section (sec. 10–A) requires that there be taken into account the extent to which the use of poison is required in the production of the article, as for example poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production.

Mr. Chairman, that is worrying about the producer and not about the consumer, and I insist that it is extremely important that if we are to have protection of the consumer from poisons such as these, that we stop worrying about the producer and worry a little more about the consumer, and particularly I feel it is your duty to place the control of legislation such as this in the hands of a department, perhaps the Public Health Service, if no other now exists, or will exist, which will not have the interests of the producer section of the population more strongly at heart than the interest of the consumers.

Most important I think is that this bill be so written, so revised that very little be left to the discretion of the Department of Agriculture, so that very little be left which can be changed subsequent to the passage of the bill through pressure brought by Congressmen or

on the President or various officials in the Government, as has been done in the past. In a speech which he made in the Senate last May, Senator Copeland said:

> There has not been a day since its introduction on the 15th of March when I have not been personally in conversation and discussion and debate with persons interested in future changes in the measure.

And a statement in an advertising publication, Advertising and Selling, told how, "as a result of many a long and secret conference which representatives of the industries concerned held with the Senator, with officials of the drug and food administration, and even with the President himself" many things in the bill were changed.

Mr. Chairman, the consumer does not have those privileges and opportunities. He is not able to go to the President and Congressmen and Senators and have his case taken care of.

If this bill is to protect the public, discretion on the part of the Secretary of Agriculture or any other official must be absolutely eliminated and control placed in the hands of the board of technologists who have no commercial interests, who are not subservient to political pressures. That can be done, and that is the only way in which the consumer can get any kind of protection.

At the last hearing there were some statements made that I would like to correct. As I understood from you, you are going to use the hearing of the previous bill in your consideration of this bill.

Senator CLARK. They are certainly available to the committee.

Mr. KALLET. I think it is important that these corrections should be made. The first relates to a statement I made during the course of my testimony at the last hearing that Senator Copeland was——

Senator CLARK (interrupting). Mr. Kallet, I warned you in the giving of your testimony that the committee did not desire to hear you indulge in personalities.

Mr. KALLET. I am not indulging in personalities. I am merely correcting the record. I am not indulging in personalities.

Senator CLARK. Your statement was immaterial in the first instance and does not require correction.

Mr. KALLET. It was not immaterial.

Senator CLARK. That may be omitted from the record.

Mr. KALLET. Mr. Chairman, these things which you are striking from the record and which you object to, I feel are extremely important to the consumers.

Senator CLARK. Mr. Kallet, the committee is not concerned in hearing you tell about your feelings at greater length at present. There are other witnesses who wish to be heard.

Mr. KALLET. I realize that——

Senator CLARK (interrupting). There are other witnesses to be heard.

Mr. KALLET. If you want to act like American prototypes of Hitler and disregard the welfare of the public and let some thousands of American citizens be poisoned and injured, you can do that.

Senator CLARK. Mr. Kallet, you will either conduct yourself in an orderly and peaceable manner or you will be ejected from the hall. The Chair will note that Mr. Kallet has been extended 50 minutes for his statement.

Mr. KALLET. I have not been able to make my whole statement. I wish it to go into the record that you have prevented that.

(Subsequent to his testimony, Mr. Kallet presented the following for inclusion in his testimony.)

CARE OF CONSUMERS' RESEARCH, INC.,
Washington, N. J., April 21, 1934.

Mr. W. G. CAMPBELL,
Federal Food and Drug Administration,
Department of Agriculture, Washington, D. C.

DEAR MR. CAMPBELL: During the course of the recent hearing on the Copeland food and drugs bill, you stated that Crazy Crystals was removed from the "Chamber of Horrors" because "* * * the manufacturers modified their advertising * * * they intended to remove all misleading advertising."

Enclosed is an advertising folder received by a drug store in New York City and distributed by it since the hearings, and also a photograph of another advertisement sent by the Crazy Water Co. with a letter dated March 26, 1934.

In view of the nature of this advertising, will not Crazy Crystals be returned to the so-called "Chamber of Horrors" exhibit?

Yours very truly,

ARTHUR KALLET.

DEPARTMENT OF AGRICULTURE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., April 27, 1934.

Mr. ARTHUR KALLET,
Crazy Water Co., care of Consumers' Research, Inc.,
Washington, N. J.

DEAR MR. KALLET: I have your letter of April 21 enclosing an advertising folder issued by the Crazy Water Co. You ask whether in view of the nature of this advertising, Crazy Crystals will be returned to the so-called "Chamber of Horrors."

We have all along been aware of the various changes made by this firm in its advertising circulars and radio announcements. The present advertising is unsatisfactory and will continue to be so long as claims are made, even by implication, for the product in excess of what could be accomplished by a cathartic and mild diuretic. Whether the feature on Crazy Crystals will be restored to the "Chamber of Horrors" for such further use as may be required of our exhibit has not been determined by the Department. That decision, I assume, will depend upon the availability of other material to illustrate more effectively the need for control of advertisements of food and drug products.

Very truly yours,

W. G. CAMPBELL, *Chief.*

[From Congressional Record, House, April 23, 1934, p. 7386]

Mr. BLANTON. Mr. Speaker, I object to any of Mr. Tugwell's philosophy going in the RECORD. In my opinion, his so-called "Tugwell bill" would have closed up every country drug store in the United States, and would have put out of business every country newspaper. He did a great injustice to a high-class, highly respected mineral-water business in my district, at Mineral Wells, Tex., which has been curing afflicted people from all over the United States for nearly a hundred years. He had this product in his "chamber of horrors" at Chicago until we forced him to take it out. I do not like his philosophy.

Senator CLARK. Henry A. Bellows.

STATEMENT OF HENRY A. BELLOWS, CHAIRMAN OF THE LEGISLATIVE COMMITTEE OF THE NATIONAL ASSOCIATION OF BROADCASTERS, WASHINGTON, D. C.

Mr. BELLOWS. If the committee desires, I will file a list of the membership of the association I represent for the record. I have not got it here.

Senator CLARK. You have that permission if you desire.

Mr. BELLOWS. The National Association of Broadcasters does not at this time desire to appear in support of, or in opposition to, any particular piece of legislation relating to foods, drugs, and cosmetics. With the principle underlying the various proposals to amend the Food and Drug Act, as distinct from the enactment of wholly new legislation on the subject, the broadcasters are heartily in sympathy. It is entirely natural that an industry which is operated under specific legal requirement to meet the public interest, convenience, or necessity should be actively concerned to see that the public is fully and completely protected against any form of fraudulent exploitation. The record of the broadcasting industry during the past year in its active cooperation with the Federal Trade Commission, as shown in the Commission's published statements, is the strongest evidence of the desire of every broadcaster to cooperate fully with governmental agencies in protecting the public.

Our purpose in coming here is, first of all, to point out certain features of S. 5 which appear to us unjust, unreasonable, or unworkable and, second, to comment briefly on the special problem which this bill would apparently create for an industry which already is operating under strict Federal regulation and only by virtue of licenses granted by the Government.

The specific detail to which I particularly want to call the committee's attention appears on page 39, lines 9 to 10, of the revised committee print of S. 5. The inclusion in this provision of the words "other than by radio broadcasting" is a deliberate, and, as it seems to us, wholly unwarranted discrimination against radio broadcasting in favor of all other forms of advertising. It says, in effect, that a dealer doing a purely intrastate business may freely use any other advertising medium he desires, including the United States mails, but he cannot use radio broadcasting without rendering himself liable to the special penalties provided in this act.

The futility of such a provision seems to us apparent. If, in fact, the use of radio broadcasting by such a dealer results in a single interstate sale, he immediately becomes liable to the penalties provided for false advertising in interstate commerce. If he does no interstate business, there seems to be absolutely no legal or social justification for having the Federal Government undertake to tell him what advertising media he should and should not use.

Senator COPELAND. Would you mind if I interjected a word? You are referring to the language on page 39, beginning at line 8?

Mr. BELLOWS. Yes, Senator.

Senator COPELAND. That relates wholly to a retail dealer who has, for example, his store in Suffern, N. Y., which is on the border of New Jersey. We desire to relieve him from difficulties so far as his purely local business is concerned, but he might be employed by some heartless concern to make use of the radio in Suffern or nearby to promote his own sales, but, of course, those waves go everywhere, so this item is intended only to relate to that particular problem.

Mr. BELLOWS. Isn't that case parallel to the Suffern newspaper, which I happen to know is read extensively in Mahwah across the border? Isn't it exactly a parallel case? I see no reason why broadcasting should be singled out for consideration of this kind since, as a

matter of fact, the case that you bring up works out if your radio station in Suffern—I do not know whether you have one there or not yet.

Senator COPELAND. We have not one.

Mr. BELLOWS. If it results in sales being made by the dealer in Suffern or across the border in Mahwah, obviously he comes right under the penalty of this act.

Senator COPELAND. If that particular retailer does, but there is nothing in the bill to prohibit legitimate advertising over the radio which goes the country over, but this applies to the retail dealer and what he can do, and it relates largely to the products which he himself makes. He might have a face cream which had in it some poison, and we knew we could not reach him so far as this bill is concerned, which relates to interstate commerce, but if he went on the radio and advertised a wonderful face cream and it resulted in great harm to the consumer——

Mr. BELLOWS (interrupting). Would not the same thing apply if he advertised in the newspaper? That would go into interstate commerce. Would not the same thing apply if he advertised on a local billboard and people driving by from other States did business exactly in the same way? We have no objection to any form of protection that you want to give in general. We do object, for the reasons which I shall bring out very shortly, to the specifiction of radio broadcasting as the one form of advertising which the local dealer may not use. We think it is an unjust discrimination. That is the whole point. It is not that we are not in full sympathy with what you are trying to do in this section.

Senator COPELAND. Don't you think that is rather captious because certainly a retail dealer would not be one merchant in 10,000 that would ever make use of the radio. Even a little station like ours up there might reach half way across the continent.

Mr. BELLOWS. On the other hand, retail dealers do make extensive use of the radio in the average small station. The retail dealer advertising for local business is the backbone of the small station's business. They are exactly the people that we contend are discriminated against in this. They can go in the local newspapers or use any other form of advertising, but they cannot use the radio. The minute they get to using radio they ar told that they are liable to the penalties of this act.

We cannot believe that it is a proper function for Federal legislation to dictate to advertisers, and above all to advertisers in intrastate commerce, regarding their choice of media. We cannot but see in this provision an illustration of the tendency which appears to run through every part of S. 5, the tendency to put all phases of the food, drug, and cosmetic business under the strictest sort of Federal regulation. This theory of far-reaching regulation is a long way removed from the principle of protecting the public against injurious or fraudulent merchandising. The broadcasting industry, already subject to stringent general regulation by the Federal Communications Commission, and to equally strict regulation as to its advertising by the Federal Trade Commission, naturally looks with some misgiving at the prospect of further regulation, based on the broadest possible grant of authority, by another branch of the Government. When the bill setting up this new form of regulation contains a provision specifically discriminating against broadcasting, although

under the circumstances such discrimination seems absolutely unwarranted, this misgiving is necessarily much increased.

The objection of the broadcasters to this particular provision can be overcome by the elimination of the words "other than by radio broadcast" in lines 9 and 10 of the bill in the committee print.

The provision just mentioned is the one specific discrimination against radio broadcasting which appears in S. 5, and consequently it is the one point on which the broadcasters at this time feel it necessary to present a definite protest. On the many sections of the bill which have nothing to do with advertising, we have, indeed, no immediate comment to make. This does not imply either approval or disapproval; it simply means that in general we feel that the subject matter of those sections concerns the manufacturers and distributors far more directly than it concerns us.

There are, however, certain matters affecting radio in this bill regarding which we welcome the opportunity to place our suggestions before your committee. The first of these is the definition of the term "advertisement" on page 3, lines 14 to 16. Even with the slight modification made in the revised draft, we feel that this definition is still so broad as to be practically unworkable if literally or exactly applied. It covers every form of verbal statement and would certainly apply to any public medical discussion in which the properties of any drug might be mentioned.

Senator COPELAND. Commissioner——

Mr. BELLOWS (interrupting). That was a long time ago, Senator.

Senator COPELAND. Well, you know you never get over a crime you have committed in your youth.

Mr. BELLOWS. I certainly believe that is so.

Senator COPELAND. We thought that by the insertion of that language that we had guarded against that sort of thing.

Mr. BELLOWS. We are grateful for small favors.

Senator COPELAND. If you have better language, I would like to hear it.

Mr. BELLOWS. I have just one suggestion.

Senator COPELAND. We sought hard to find the language.

Mr. BELLOWS. We have one proposal. Such a definition is manifestly inaccurate, and we urge that the word "commercially" be inserted after the word "opinion" in line 15.

If that word is put in, then I would entirely agree, and I agree that you have immensely improved it over the original draft, and I say we are very grateful, but I think that word ought to go in.

While we are on this matter of definitions, permit me to point out that the definition of "drug" on page 2, lines 13 to 15 of the committee print, is so broad as to include eyeglasses, corsets, and almost any device that may be worn.

This is the point that Senator Clark brought up, and I would like to comment on it. Since it seems utterly absurd to include, for example, orthopedic shoes as "drugs", it seems apparent that this definition ought to be modified, or else that there should be a proviso making specific exclusions.

In other words, there should be a specific definition. As the bill stands, orthopedic shoes would be drugs, and anything else can be anything else under this bill.

Senator COPELAND. If you read the fifth line "for the purposes of this act".

Mr. BELLOWS. If that is true, anything in this act could be anything else. It seems to me that it is absurd to extend the word "drug" to cover things of that kind, and that is certainly a violation of the English language, and I wonder what will happen to it in a court construction. If it is the desire of the committee and Congress as I think it undoubtedly is and should be to have this act cover certain appliances, it seems to me they should be defined as something besides drugs.

Senator COPELAND. You know, Commissioner, it is a fact, although it has not been brought to your attention. You have spoken about shoes. The most extravagant claims are made about this or that shoe, about removing pressure on the spinal nerves, or relieving posture of people, curing headache and anemia and all sorts of things.

Mr. BELLOWS. I know; I bought a pair once and I quite agree with you.

Senator COPELAND. Your point is that it is incongruous to have it like this, but you would like to have that divided to put these devices in another definition.

Mr. BELLOWS. Exactly. We have every reason to agree with the committee including devices of that kind within the provisions of the act. I simply raised the question which Senator Clark already raised, whether you can define them properly as drugs. And exactly the same thing applies in the next definition as to cosmetics, which as it stands reads:

> The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.

The same difficulty applies to that definition of "cosmetic" on the same page. This definition would include, if literally applied, such "substances intended for promoting the attractiveness of the person" as earrings and other jewelry.

Senator COPELAND. By putting in the word "physically" for instance?

Mr. BELLOWS. I suggest that the phrase should be, "Intended for external application in cleansing or altering."

Senator COPELAND. You are not a doctor?

Mr. BELLOWS. No, not even a lawyer.

Senator COPELAND. Some of them go even further than that.

Mr. BELLOWS. It is suggested that after the word "for" in line 17 of page 2 of S. 5 there be inserted the words "external application in", though even this does not entirely obviate the difficulty to which I have referred.

Still another definition given in the bill concerns the broadcasters very directly. This is the definition of false advertising given on page 23, lines 22 to 24, and page 24, lines 1 to 5, of the committee print. The definition of false advertising as given in the first four lines of this paragraph seems entirely adequate, and the additional material contained in the second sentence appears not only unnecessary but very confusing.

You observe that I am objecting to it for exactly the opposite reasons that Mr. Kallet advanced. He objected because he could not find particulars in certain advertising that were wrong. I am objecting to it because you may find some small particular which is susceptible of at least a doubtful interpretation.

The inclusion of the phrase "in every particular" would make almost every advertisement now regarded as wholly legitimate open to attack, and the phrase "substantial medical opinion" is rendered obscure by the definition of medical opinion on page 3, lines 18 to 23. It is suggested that this second sentence might well be stricken out.

That is not from our standpoint a very serious difficulty, but it is one of the things that should be considered.

Senator COPELAND. Do you agree with Dr. Jordan's suggestion "disseminated through any medium whatsoever" to be added?

Mr. BELLOWS. I have no objection to that although your definition of "advertisement" on page 3, lines 14 to 16, is so inclusive that I cannot see any possible need of it. If you think it makes it stronger by putting it in twice, I have no objection. It is already in.

The provision appearing on page 24, lines 12 to 15, of the committee print, illustrates clearly the reason why the broadcasters, in common with other advertising media, regard this bill with misgiving. It gives the Secretary of Agriculture practically unlimited power to add at will to the list of diseases for which drugs may not be advertised as having any therapeutic effect. There was much criticism of the list of diseases, included in the bill as it was drafted last year, for which it was declared unlawful to advertise cures, but in many ways it is even more disconcerting to give to any Government official such arbitrary power that he can, almost at will, destroy an entire advertising campaign. The word "therapeutic" is by definition so broad that it covers not only cures but also palliatives. It is, therefore, suggested that the clause, "as well as any other disease which may be added to this list by regulations as provided by sections 701 and 703" might well be omitted.

I think, Senator Copeland, that you said this morning that Congress could itself make additions to that list.

Senator COPELAND. I was always out of sympathy with that long list that was published last year. We went over this matter very carefully in the selection of these particular diseases, as there had been great exploitation of the public, and it is my own view, purely personal, that we might well stop at the end of line 11 omitting the rest, because if in the progress of medical science it is determined that some other diseases should be put into this category, it could be added. That could be done by an amendment to the bill. It might happen—I should not think it would happen, but it might happen that this committee that we have set up here might decide to put in everything from asthma to zymosis. So far as I am personally concerned, I would be willing to cut those four lines out following "heart and vacular diseases".

Mr. BELLOWS. Senator Copeland has expressed my feeling about the matter so much better than I could, that I will drop that point. That is the way we feel.

The general criticism of the provision just cited, that it confers alarmingly vague but broad powers on the administering body, applies in principle to the entire section of the bill which begins on line 1 of page 27 of the committee print and continues through line 19 of page 31 of the committee print. These provisions appear to contemplate a sort of government by committee, involving the delegation of very important legislative and administrative authority to groups which

are virtually without responsibility. While it is not clear just how much authority is vested in these bodies, the bill sets up two administrative and five advisory committees with vague but apparently considerable power. It is not clear whether the members of these committees are to receive pay for their services, nor is there any provision regarding publicity for their actions.

The delegation of broad powers to such bodies necessarily would create confusion and take away from the properly constituted and permanently established branches of the Government much of the responsibility which they ought to accept. Furthermore, if these committees are to function usefully, it will obviously involve considerable expense, for which the bill makes no provision.

Senator COPELAND. Just a moment. You were not in the hearings last year on the original bill?

Mr. BELLOWS. Oh, yes.

Senator COPELAND. Do you remember at that time the great agitation there was against conferring this power upon the Secretary?

Mr. BELLOWS. Yes.

Senator COPELAND. We realized there had to be somebody to make regulations and so we thought this would be a happy way to solve it, to have this scientific committee pass upon these matters with public hearing and so forth before they should be promulgated, and that no regulation should be promulgated until it received the approval of the majority of the committee.

Mr. BELLOWS. Expressing purely my personal view of the subject, because I have not discussed this matter with broadcasters, I feel very strongly that the more definitely the Congress itself can determine in the bill what the regulations are to be and can make, not the administrative rules, but the general principles clear in the bill, and by amendments thereto which are always possible, the better it is going to be. Having served as a member of a much-abused executive committee of the Government when I was on the Radio Commission, I know from my own experience how easy it is when you have no very specific instructions, to go astray, and how far beyond and far outside of what the law provides, and the thing that we are afraid of in this system of government by committee, as I have called it, is that these committees, set up with a very vague definition as to what they are to do, whether they are purely advisory, whether they have any responsibility or not, may make complications, and I would like to point out finally that the proviso contained in lines 15 to 19 on page 31 seems to be sufficiently broad to render the work of the advisory committees practically useless, if the Secretary sees fit to disregard them.

In other words, after setting up the committees, there is the proviso:

> That nothing in this paragraph shall be construed as restricting the responsibilities and powers conferred upon the Secretary by this act—
>
> Lines 15 to 19 on page 31—
>
> and no plans shall be accepted which are designed to promote monopolies or eliminate or oppress legitimate enterprise.

In other words, with all this important structure of committees, if the Secretary does not like what they suggest, he goes ahead and does what he wants, and it is exactly that indeterminate situation that we regard with misgiving, which is as strongly as I care to put it.

A similar objection applies to the provision on page 41, lines 8 to 13, of the committee print. This section gives such broad powers to the Secretary of Agriculture in the formulation of regulations for hearings as to provide practically no measure of protection to those who are cited for alleged violations of the act. The Secretary might, under this provision, establish regulations which would in effect deprive many such persons of the opportunity which the section is supposed to guarantee. It is urged that this section be made more specific, particularly as to the time which must elapse between the notice of a hearing and the date of the hearing itself.

That is the particular detail that I have in mind, that there should be a specific and adequate amount of time between the notice of hearing and the date of the hearing.

Many of the difficulties to which I have referred in connection with S. 5 are likewise to be found in S. 580, which is also before your committee for consideration. In both bills there seems to us to be the same underlying theory of complete Federal regulation of every branch of the food, drug, and cosmetic industries, the same tendency to throw away the structure which has been built up over a period of nearly 30 years on the basis of existing law, and the same delegation of vaguely defined powers to the administering authority. In both bills, there are many blanks to be filled in by the Secretary of Agriculture, and the effect on the broadcasting industry is bound to depend largely on what regulations the Secretary chooses to write into those blanks.

Above all, both bills appears, so far as advertising is concerned, to create a new regulatory agency. It does not appear from the terms of either of them that the authority of the Federal Trade Commission will be materially reduced. The Commission will still act in all cases where there is the allegation that false advertising constitutes unfair competition. The bills before you simply double the machinery for the control and regulation of advertising, and do it in such a way that the new regulatory body can pretty nearly determine for itself the limits of its own power.

In presenting these suggestions the National Association of Broadcasters once again wants to make it clear that its primary concern is with such features of S. 5 as appear to create a new and additional form of regulation for the broadcasting industry. We are particularly concerned when that regulation, by an express provision of the law, discriminates directly against radio broadcasting. Again let me point out that broadcasting is already subject to direct regulation by the Federal Communications Commission and the Federal Trade Commission, and that the setting up of a third regulatory body seems to us to involve needless confusion and expense. At the same time, we have become so used to being regulated by the Government that we can undoubtedly get along with more of it, provided we have reasonable assurance that the new machinery will not be set in motion with a direct Congressional mandate to discriminate against broadcasting. It is because such a mandate apparently exists in the bill as it stands, and because the general provisions of the bill leave so much to the discretion of the proposed new regulatory body, that we appear before you at this time to make our position clear.

Senator COPELAND. Mr. Bellows, for myself I am very keen to make sure that this institution of criminal proceedings is safeguarded,

and if you will remember that Mr. Dunn this morning suggested an amendment. We would be happy and I am sure I speak for the whole committee in saying this, if you have any language that ought to be added or any change in the section 710, we would like to have it.

Mr. BELLOWS. I would like an opportunity to study Mr. Dunn's recommendation. As I listened to it, it sounded entirely reasonable, but it is very hard to tell about those things until you sit down and look at them. I would like to say without having studied it but having listened to it, that it seems to meet our objection.

Senator COPELAND. I think it does, but I want you to be sure of it.

Mr. BELLOWS. If in reading it over I find it does not, may I file a statement on that point with the committee?

Senator CLARK. The record will be held open for several days after the conclusion of the hearings, and anybody desiring to file further information may do so.

Mrs. Hardy.

STATEMENT OF CATHERINE T. HARDY, REPRESENTING CHICAGO AND COOK COUNTY FEDERATION OF WOMEN'S ORGANIZATIONS

Mrs. HARDY. Gentlemen, I won't take but just a moment. I represent 68 groups in Chicago and Cook County Federation of Women's Organizations, a fairly cross section of the consumer in our community, of about 50,000 women. I would like to go on record as saying that we endorse this bill and hope for its speedy passage.

Senator CLARK. Miss Eichelberger. I understand that you desire to make a statement on behalf of another organization than that which you represented this morning?

Miss EICHELBERGER. I do. I am the director of the Nutrition Service and Evaporated Milk Association, representing the biggest part of that industry. We heartily endorse this bill as it stands, and are also hoping for a very speedy passage.

Thank you.

Senator CLARK. Mr. Robb.

STATEMENT OF CLINTON ROBB, CONSULTING COUNSEL, UNITED MEDICINE MANUFACTURERS OF AMERICA, INC.

Mr. ROBB. Mr. Chairman and Senators, I appear on behalf of the United Medicine Manufacturers of America, one of the largest trade organizations in the field of proprietary medicine preparations.

The statement I am about to make will be based largely upon changes that have been made in S. 5 from the provisions of S. 1944 and S. 2800.

Senator CLARK. You mean of the last Congress?

Mr. ROBB. Yes. And also upon changes which have been made in S. 5 itself since it was introduced.

In this statement I will say at the outset that I am going to endeavor to be constructive where I am critical and to make specific suggestions in an effort to be of assistance to the committee in its labors.

I am opposed to S. 5 not only for reasons advanced in hearings on S. 1944 and S. 2800, the original Tugwell bills, but because I regard the pending bill as in some respects more unfair and objectionable than its predecessors, after which it is patterned in general plan and purpose, and believe its revised wording has made it more objectionable than when introduced.

Briefly my criticism of S. 5 is that (1) the bill would give the Secretary of Agriculture dictatorial powers over the affairs of those who manufacture and sell proprietary preparations and would permit the future sale of such preparations only at his sufferance; (2) the bill would imperil the inherent and valuable right of the public to practice self-medication within reasonable limits and to be supplied with prepared or proprietary medicines essential to the practical exercise and enjoyment of that right; and (3) it would make possible and even probable the confiscation of a great industry developed in strict compliance with congressional acts and now supplying a highly beneficial public service, the right both to give and to receive which the Congress has recognized.

When considering S. 5 it should be kept in mind that the medical viewpoint is that practically all drugs are dangerous unless administered under the supervision of a physician and hence that, except in a few instances involving comparatively trivial ailments, self-medication is dangerous and should be suppressed; and that public statements of the Department of Agriculture, whose views on drug questions are those of medical advisors, reflect that position.

Section 401 (a) (1) of the pending bill, as shown in Committee Print No. 3, provides that a drug is adulterated, "if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof". Then follows language not in S. 5 originally introduced and which enumerates four specific instances in which a drug may be adulterated other than through "the conditions of use prescribed". These additions to S. 5 as originally drawn justify if they do not compel the inference that the purpose of this paragraph is not merely to promote the purity and high standards of drugs, as to the propriety of which there can be no question, but rather to make possible administrative rulings to the effect that a drug is adulterated if it may be dangerous to health because it involves self-medication.

Such a provision has no proper place in statutory references to adulteration, since it really involves a question of misbranding. If the true purpose of this paragraph is the laudable one of protecting the purity of drugs the language should be so changed as to clarify its meaning and provide that a drug is adulterated if it is impure in any of the four enumerated instances, or otherwise.

Senator COPELAND. Would you consider that it was bad to take if it was filthy and putrid?

Mr. ROBB. I certainly would.

Senator COPELAND. And if it has been prepared under unsanitary conditions?

Mr. ROBB. It should not be permitted on the market if it is unfit.

Senator Copeland. And if its container is composed of substances which may be harmful or dangerous to health?

Mr. ROBB. Certainly.

Senator COPELAND. And if it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations?

Mr. ROBB. Certainly.

Senator COPELAND. Then what is your objection?

Mr. ROBB. My objection is to the manner in which it is stated.

Senator COPELAND. Could you possibly find a language that would suit you?

Mr. ROBB. Yes.

Senator COPELAND. Will you suggest it?

Mr. ROBB. May I repeat my statement that such a provision has no proper place in statutory references to adulteration, since it really involves a question of misbranding. If the true purpose of this paragraph is the laudable one of protecting the purity of drugs the language should be so changed as to clarify its meaning and provide that a drug is adulterated if it is impure in any of the four enumerated instances, or otherwise.

That, Senator, I submit, would accomplish your purpose and still not imperil the right of self-medication.

Senator COPELAND. I do not see how self-medication enters into it.

Mr. ROBB. I think it is behind the whole thing. If you will indulge me, Senator, I expect to demonstrate that here this afternoon.

Senator COPELAND. I hope you will. I will be interested to have it demonstrated. As far as I am concerned, it does not enter into it at all.

Mr. ROBB. I expect to convince this committee that it is the most important thing before it.

Section 402 (f) provides that a drug is misbranded if its labeling fails to bear plainly and conspicuously—

such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 703, against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application.

As originally drawn this provision is S. 5 was against use in such pathological conditions or by children where such use "is contraindicated and may be dangerous to health", but in the reprint the words "is contraindicated and" are eliminated, so that under the bill as now drawn a drug may be declared dangerous to health although it is not contraindicated.

Senator COPELAND. You have set up a straw man and you are proceeding to knock it down. Where is this language that you speak of? Call if specifically to our attention. If there is a defect in the bill, the committee would desire to correct it.

Mr. ROBB. To repeat: As originally drawn this provision in S. 5 was against use in such pathological conditions or by children where such use "is contraindicated and may be dangerous to health", but in the reprint the words "is contraindicated and" are eliminated, so that under the bill as now drawn a drug may be declared dangerous to health although it is not contraindicated.

Senator COPELAND. You have already stated that.

Mr. ROBB. That is necessary to my explanation. I object to the change in the specific elimination which I have enumerated.

Senator GIBSON. That is, to the elimination of the language you have designated.

Mr. ROBB. Yes.

Here again the implication is that the underlying purpose of this bill is to make possible rulings to the effect that a drug may be dangerous to health because it involves self-medication and does not cure or give absolute or permanent relief from some ailment or condition.

Section 601 (b) now provides that—

For the purposes of this act the advertisement of a drug for sale in interstate commerce, representing it to have any therapeutic effect in the treatment of cancer, tuberculosis, venereal diseases, heart and vascular diseases, as well as any other disease perilous to the life of the individual or to the public health which may be added to this list by regulations as provided by sections 701 and 703, shall be deemed to be false.

And so forth.

This wording represents the addition to this paragraph as originally drawn of the words "perilous to the life of the individual or to the public health", which added words clearly indicate that this paragraph contemplates the addition to this list of forbidden diseases not only those maladies which may be declared "perilous" to the public health in general but which may be "perilous" to some individual who, because of an idiosyncrasy or hypersensitivity, may have what is technically known as an allergic condition that makes him peculiarly and abnormally susceptible to the influence of some drug not harmful to the ordinary person; and it is well known that there are few effective drugs capable of safe use by the general public that may not be harmful in some degree to a comparatively insignificant number of abnormal individuals and to whom that drug might be "perilous". This wording of the bill thus supplies further evidence that it is most perilous to self-medication.

Senator COPELAND. Let us assume that those words are coming out, that lines 12, 13, 14, and 15 may be deleted.

Mr. ROBB. That is good news to me.

Senator COPELAND. Then would your criticism disappear?

Mr. ROBB. Not entirely. That would largely meet my criticism.

Senator COPELAND. Proceed, please.

Mr. ROBB. Under section 701 (a)—

Authority to promulgate regulations for the efficient enforcement of this act, except as otherwise provided in this section, is hereby vested in the Secretary.

Section 703 (a) provides that for the aid and advice of the Secretary "in promulgating regulations for the public health", as contemplated among others by the sections just mentioned

A Committee on Public Health is hereby provided which shall consist of five members designated by the President with a view to their distinguished scientific attainment and interest in public health with respect to food, drugs, and/or cosmetics and without regard to their political affiliation.

Obviously this section 703 (a) contemplates a board of outstanding physicians and public-health officers who would be favorably committed in advance to the idea that all proprietary medicines intended for self-medication are inherently more or less dangerous and should be removed from the market. The life expectancy of self-medication under such a board and under such a mortuary table as this bill would provide would not be great.

While, in the present stage of science, it might be in the interest of the general public conditionally to exclude from the permissible scope of self-medication certain maladies for which no successful drug treatment yet has been developed, such exclusion should be made by Congress and power to revise or extend any such list of forbidden diseases should belong exclusively to Congress. For the same reasons, Congress should safeguard the right of self-medication by providing that any committee or board created under the Food and Drugs Act

shall not be dominated or controlled by the medical profession. Because the interests of the medical profession necessarily conflict in some degree with those of manufacturers of proprietary medicines, and, since it is fundamental that no man should sit in judgment of a case in which he has even an indirect interest, no committee or board that is to assist the Secretary of Agriculture or pass upon administrative acts should be composed exclusively of physicians. The public interest can be fully protected and the right of self-medication preserved at the same time by provisions either limiting the number of physicians on such committee or board or requiring the appointment of some nonmedical members who shall be disinterested.

Another instance which tends to support my contention that section 5 as now written is even worse than when originally introduced and is fully as objectionable as the original Tugwell bills, is to be found in section 711 (e) which provides in part that:

> In cases of articles of food, drugs, or cosmetics seized under the provisions of this section when the same issues of adulteration or misbranding under the provisions of this act, raised by the same claimant, are pending in various jurisdictions, the United States District Court for the district where one of such seizures is pending which is nearest to the place of business of such claimant is hereby vested with jurisdiction to try such cases separately; and on application of the claimant, seasonably made, may be tried in such jurisdiction. Separate verdicts shall be rendered in each case and judgments entered on such verdicts in conformity with the provisions of this section.

Under the language just quoted, and which has been added to S. 5 as originally drawn, it will be observed that by necesssary inference this section of the bill now recognizes the right of the Department of Agriculture to cause to be made an unlimited number of seizures throughout the United States and involving "the same issues" of misbranding, provided only that those identical issues shall be tried in the district court nearest the claimant's place of business. In other words, the sole consolation given by this paragraph to a claimant of goods that may have been seized in every State in the Union in which he may be doing business, under labeling which presents exactly the same issue in every seizure case, is that he may have his rights determined by the Federal court nearest to him.

Language hardly could be found that more clearly reveals the thought and purpose which underlies this whole bill. If one seizure case presents the issue of misbranding in dispute or which the Department feels should be subjected to judicial review, and no imminent danger to the public is involved, where is there any justification or satisfactory explanation of multiple seizures that can have no purpose and effect other than to harass, annoy, and intimidate manufacturers of drug products and induce them to yield to arbitrary and capricious administrative rulings rather than suffer the destruction of their business. What is the practical value to a manufacturer or distributor of prepared medicines of a day in court after his business has been destroyed through multiple seizures? Why not give him a hearing before the business is destroyed? Certainly this would be more in harmony not only with established principles of legal procedure but with one's sense of justice and fair dealing.

One of our Federal courts has just decided a case under the Food and Drugs Act which, I submit, well illustrates my contention not only that a statute which merely gives the manufacturer of prepared medicines his day in court may fall far short of providing adequate protection of his rights but that the present Food and Drugs Act, instead of giving a manufacturer more leeway than he should have, actually places him under a serious handicap in the protection of his rights and subjects him to official duress. While the claimant involved in that case obtained a favorable ruling and thus prevented the destruction of its business, because that particular claimant happened to have the financial resources essential to litigation with the Government, a smaller manufacturer or one less favorably circumstanced might have been compelled to yield to departmental demands which this Federal judge found unreasonable as matter of law.

The ruling to which I refer was made on February 2 of the present year by Judge Merrill E. Otis of the United States District Court for the Western Division of the Western District of Missouri in the case of *United States* v. *Gizzard Capsules*, a product of the George H. Lee Co. of Omaha, Nebr. Judge Otis there rejected the contention of the Food and Drug Administration to the effect that a medicine may not be advertised "For" an ailment or condition unless capable of giving absolute or complete relief from that ailment or condition. The claimant or manufacturer of the product involved attempted to persuade the Food and Drug Administration that its product was not misbranded because it tended to lessen the injury and was capable of beneficial use in some degree in the conditions for which it was sold. While the Department declined to discuss the claimant's contention and conclusion outside of court, Judge Otis observed in upholding the position of the claimant "I cannot believe that anyone reasonably could question that conclusion."

I refer to this case solely for the purpose of supporting my view that the Congress, in whatever changes it may see fit to make in the present Food and Drugs Act, should do more than merely provide a day in court for a manufacturer or distributor of proprietary preparations who honestly differs with the Government as to the truth and accuracy of his claims and representations. I have in mind particularly the interests of the manufacturer or distributor whose business may be small or who may be less favorably circumstanced as to capital and resources. Though he may be convinced of the truth of his labeling and advised that his claims and representations do not violate the law, he may be in no position to keep alive the commercial spark while he is fighting for his rights or be without means to wage a legal battle against the Government, so that he must choose between the short end of a hard bargain with the Department and the destruction of a business which, however small or humble, may represent substantially all his worldly possessions. Here again "the concessions of the weak are the concessions of fear", and I submit that the Congress should not only provide a day in court for those who dispute administrative rulings but should make it possible for a manufacturer or distributor to obtain a summary and informal review of administrative acts that shall be binding and preserve the status quo pending any review that may be sought in the courts.

For reasons already outlined, I favor the creation by the Congress of a disinterested board of review empowered and directed to give summary consideration not only to threatened prosecutions under the Food and Drugs Act but to threatened administrative acts of the Food and Drug Administration. An administrative board of review is provided in the Dunn bill, introduced by Senator McCarran as

S. 580, but that bill provides merely for review of threatened prosecutions by a board that shall be "impartial." My position is that if a board of review is created by the Congress that board should be free from control by the medical profession and should have power to review all administrative acts which do not involve protection of the public from imminent danger to health. Moreover, I believe the right of appeal to that board should be made absolute unless denied by unanimous vote of the board, rather than restricted to cases in which the board may grant appeals as now provided in S. 580. This would prevent frivolous appeals yet preserve the right of any party whose case has apparent merit sufficient to persuade some members of the board that it should be reviewed.

Another serious objection to S. 5 is that it would give to the Food and Drug Administration, whose viewpoint is that of physicians or officials primarily concerned with technical and scientific questions, the censorship of advertising used independently of the package and which, save in those relatively few cases which involve protection of the public from imminent peril to health, present questions of fact and fair dealing that properly call for consideration by a board or agency not only familiar with the technique of advertising but with the principles and rules by which the fairness of trade policies and practices in general are to be measured. I am convinced, for reasons I have tried to make clear in this discussion, not only that the review of advertising of proprietary preparations independently of the package should be committed to the Federal Trade Commission, which has been doing this very work effectively for some time and has developed adequate machinery to that end, but that the Federal Trade Commission should not be bound in its decision in such cases by the medical reports that may be submitted to it by the Food and Drug Administration. The bill introduced in the House by Congressman Mead, or H. R. 3972, provides for the censorship of such collateral advertising by the Federal Trade Commission, except in instances in which imminent danger to health may be involved, but the bill fails to give the Commission the independence I feel it should have. Specifically, I think that any bill which confers power on the Federal Trade Commission to consider the collateral advertising of proprietary preparations should provide that, while the Food and Drug Administration may submit to the Federal Trade Commission its views on medicinal or therapeutic questions, those views and reports shall be accorded only such weight and recognition as the Commission may see fit to give them in view of all the evidence in the case. The medical viewpoint should not dominate and control in questions in which the profession has an interest. The proprietary medicine industry asks only that the jury before whom it argues its case be not selected from those who would profit from the suppression or curtailment of the right of self-medication.

I also am opposed to those provisions in S. 5 or other pending bills which, in my judgment, tend to destroy the distinction between interstate and local commerce which the Constitution enjoins upon all Federal activities. Manufacture and production are not even commerce, much less interstate commerce, and become the proper subject of Federal consideration, officially and judicially, only after they have been shown to constitute a step or stage in the unlawful transaction of interstate commerce. If S. 5 provided in effect that, upon substantial evidence tending to show interstate violation through a connected transaction which appeared to have had its initial stages locally, the Department of Agriculture should have access to factories and business establishments in which the products involved were prepared for or started on their interstate journey, such a provision might square with the Constitution and judicial decisions thereunder. But the language of section 707 (a), which deals with "factory inspection", falls far short of meeting this test of legality, for it provides:

SEC. 707. (a) In order adequately to protect public health and welfare through enforcement of the provisions of this Act, officers or employees duly designated by the Secretary, after first making reasonable request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce or are held after such shipment, or to enter any vehicle being used to transport such food, drugs, or cosmetics, in interstate commerce; and (2) to inspect such factory, warehouse, establishment, or vehicle and all equipment, finished and unfinished materials, container, and labels there used or stored.

The change made in this paragraph since the bill was originally introduced is most significant. As first drawn S. 5, like its predecessors S. 1944 and S. 2800, stated the purpose of factory inspection to be "to regulate interstate commerce in food, drugs, and cosmetics and enforce the provisions of this act." Apparently appreciating the fact that the real effect of the bill would be to regulate local or intrastate commerce, and seeking to rest its powers upon a movable base, the proponents of this bill have substituted for "regulate interstate commerce in food, drugs, and cosmetics" the elastic words "protect public health and welfare", hoping thereby to avoid constitutional limitations. Federal factory inspection of sanitary conditions that are a part of interstate commerce may be desirable and lawful, but the extension of interstate commerce to manufacture and production, under the guise of a health measure, would be another step toward wiping out State rights by destroying the boundary lines between State and Federal powers.

Plainly, by reasonable if not necessary inference, this paragraph of the bill authorizes a fishing expedition into the private business affairs of a manufacturer by a representative of the Department upon mere suspicion that something may be caught whereby to justify an interstate seizure. To speak bluntly and directly, this places the cart in front of the horse, reverses the usual order of legal proceedings, and constitutes a plain invasion by the National Government of a field which our Constitution reserves to the several States and to their local subdivisions. Inasmuch, to quote from the opinion of Justice Holmes in *Federal Trade Commission* v. *American Tobacco Co.*, 264 U. S. 298, "We cannot attribute to Congress an intent to defy the fourth amendment, or even to come so near to doing so as to raise a serious question of constitutional law", I feel sure this committee will give serious consideration to the contention I have just made that section 707 (a) of S. 5 exceeds constitutional limitations as to Federal powers by invading the field of production, and that the committee will apply this criticism when considering other food and drug bills that have been or may be introduced.

Other provisions of S. 5 are objectionable to me for substantially the same reasons I have advanced with respect to the particular provisions that have been mentioned, but those provisions have been so

ably discussed by other witnesses that I do not feel warranted in consuming the time of this committee by mere repetition.

To summarize my constructive suggestions, if changes in the existing statute are decided upon, I would—

1. So amend the Food and Drugs Act as to cover cosmetics and medical appliances.

2. Create a board of review, a majority of whose members would be nonmedical and disinterested persons, to consider appeals from threatened prosecutions and administrative acts of the Department of Agriculture.

3. Give the Federal Trade Commission exclusive jurisdiction over advertising independently of the package, except in cases involving imminent danger to the public, the term "danger" being carefully defined.

4. Make the Federal Trade Commission independent of the Food and Drug Administration in its consideration of such collateral advertising.

5. Forbid more than one seizure of a misbranded drug upon the same issue where there is no immediate danger to health.

6. If factory inspection is found desirable, limit such inspection to sanitary conditions which form a part of interstate commerce.

7. Provide that the promulgation of regulations under the Food and Drugs Act shall be limited to the enforcement of the express or necessarily implied provisions of the statute.

8. Require reasonable notice by publication of all new regulations and new interpretations of the statute or regulations.

In conclusion I submit that, if these changes were made in existing laws, the public interest would be fully protected without injustice to any of the parties involved.

I thank you.

Senator CLARK. Mr. Falk.

STATEMENT OF ALFRED T. FALK, ADVERTISING FEDERATION OF AMERICA

Mr. FALK. I merely wish to place the Advertising Federation of America on record as urging prompt passage of Senate bill no. 5 as revised, either with or without some of the constructive amendments suggested by representatives of the industries.

Senator COPELAND. Judge Goodwin, do you desire to make a statement?

Mr. GOODWIN. Mr. Chairman, I had one matter to present, and I wondered if I could defer that until the next meeting. I see that there is another matter that I wish to comment on. May I defer that to the next meeting?

Senator COPELAND. Why do not you make your statement now, Judge?

Senator CLARK. Mr. Snyder.

Mr. SNYDER. I will file a brief.

Senator CLARK. Very well.

Mr. GOODWIN. I will make this suggestion now, if I may, Mr. Chairman?

Senator CLARK. Yes; proceed, Judge.

STATEMENT OF CLARENCE N. GOODWIN, ALLIED MANUFACTURERS OF THE BEAUTY AND BARBER INDUSTRY

Mr. GOODWIN. My name is Clarence N. Goodwin. I am appearing on behalf of the allied manufacturers of the beauty and barber industry.

There are two things, Mr. Chairman, that have occurred to me. One of them suggested itself during the hearing; the other I had given some thought to. On page 25, section 701–A, under the Power to Make Regulations, it is provided:

> The authority to promulgate regulations for the efficient enforcement of this act, except as otherwise provided in this section, is hereby vested in the secretary.

Now I have assumed, and I think everybody has assumed, that all that section meant was that wherever, in the act, authority to promulgate regulations is given, without specifying who is to promulgate them, that authority is vested in the Secretary of Agriculture. It did not occur to me until this hearing that it might be susceptible to a different interpretation, namely, authority to promulgate any regulations which might appear to be in the interest of the efficient enforcement of this act.

I do not know whether I make myself clear, because the thought has just occurred to me now and I am probably not stating it with very much clarity, but our thought has been, and I think it is the thought of everybody, that as there are specific regulations referred to in the various sections of the act, that was the only authority conferred upon the secretary, namely, to make the regulations that had been specifically enumerated, and that the only purpose of this section was to make it clear that that authority was vested in the secretary and not in somebody else.

Now, if the chairman and members of the committee please, if that is not clear it ought to be made clear, and I will take the liberty to make the suggestion in writing with a memorandum supporting it.

Senator CLARK. That may be done.

Mr. GOODWIN. Now, assuming that I am right about the meaning of section 701 (a), there is another matter that has occurred to those interested in the cosmetic industry, that we think is important. According to the interpretation that I have just stated, the only authority to make regulations at the present time with reference to adulterated cosmetics, or with reference to cosmetics generally, is that contained in section 503, which is to the effect that "The Secretary is hereby authorized to promulgate regulations, as provided by sections 701 and 703, for the certification of coal-tar colors which are harmless and suitable for use in cosmetics." Now it occurs to us that that power of the Secretary ought to be broadened, and can be broadened in such a way as not to invite any justifiable criticism on the part of the members of the industry.

What we submit is this: insert after section 503, on page 23, the following:

> Regulations governing the labeling of cosmetics. Section 504. The Secretary is hereby authorized to promulgate regulations, as provided in sections 701 and 703, requiring cautionary statements to be included in the labeling of a cosmetic in cases where such requirement is reasonably necessary for the protection of health.

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You will note, Mr. Chairman and members of the committee, that this provision with reference to labeling and cautionary statements does not confine itself to cosmetics which may be considered injurious to health on account of some poisonous or deleterious ingredients, but would permit the Secretary to make regulations requiring cautionary labeling wherever, in connection with any cosmetics, such caution appeared to be necessary. It is an extension of the power of the Secretary, and it ought not, it seems to us, invite opposition. It is, we think, a constructive suggestion and not one that is controversial. If that is adopted then it will be necessary to amend section 703 by inserting in line 12 on page 27 the words, "Section 504;" before the words, "and section 601."

Unless there are some questions to be asked, that is all I wish to say at this time.

(Letter received from Mr. Goodwin is as follows:)

GODWIN, SMITH & ELY,
Washington, March 11, 1935.

The Honorable Members of the Committee on Commerce, United States Senate:

GENTLEMEN: In making a statement before your committee on Saturday, March 2, I presented a number of suggestions with reference to amendment to the present draft of S. 5, and now, in accordance with permission given, I am submitting this memorandum in support of those and other suggestions relative thereto.

With reference to cosmetics, I suggested that the Secretary be given authority to promulgate regulations requiring cautionary statements in the labelling where the protection of health might demand. The amendments proposed were as follows:

Insert on page 23, after line 19, the following:

"REGULATIONS GOVERNING THE LABELLING OF COSMETICS.

"SEC. 504. The Secretary is hereby authorized to promulgate regulations as provided in sections 701 and 703, requiring cautionary statements to be included in the labelling of a cosmetic in cases where such requirement is reasonably necessary for the protection of health."

Amend section 703 by inserting in line 12, on page 27, the words "section 504;" before the words "and section 601".

This suggestion was made for the reason that there may well be cases where the protection of users demands that a caution be given the public with reference to the method of using or applying a cosmetic and informing the public that the useof the cosmetic ought to be avoided under certain stated conditions.

While in such cases competing manufacturers may be perfectly well aware of the need of such cautionary notice, there is a natural reluctance on the part of each to adopt such cautionary labelling voluntarily. It is quite easy to understand that if a manufacturer were to place a cautionary notice on its own product, this might and often would give competitors an opportunity to point out this fact as an argument that the product must be inherently dangerous, whereas might well be that, when properly applied, it was entirely innocuous and, in any circumstances, the safest and best of all the cosmetic preparations of that character.

Nothwithstanding the reluctance of the individual manufacturer to adopt such labelling voluntarily and alone, it will, it is believed, in most, if not in all, cases, gladly welcome such a regulation and willingly comply with it. Moreover, it is obvious that where such labelling is reasonably necessary for the protection of the health, it should be required by an authorizing regulation, whether desired by manufacturers or not.

While the amendment would give the Secretary power to make such regulations, the question of when, if at all, he would exercise it would, of course, be a matter within his discretion. It may be noted that, under the amendment proposed, the power of the Secretary would not be limited to cases of cosmetics containing poisonous or deleterious substances, but would extend to every case where the protection of the public required such cautionary labelling.

At the same hearing, I suggested that while the intention of section 701 (a) was apparent, it might hereafter be misinterpreted. The specific language of the section is as follows:

"SEC. 701 (a). The authority to promulgate regulations for the efficient enforcement of this act except as otherwise provided in this section is hereby vested in the Secretary."

There are throughout the bill a large number of provisions providing for regulations in certain specified cases. It is apparent that it is the purpose of the bill to cover by such specific provisions every instance in which authority to make regulations, is to be granted, and that the actual intention of the section in question is to make it clear that wherever there is any authority provided in the bill for the making of regulations, that authority is to be exercised by the Secretary alone, except in the case of regulations provided for in section 714, which relates to imports, and vests a joint authority in the Secretary of Agriculture and the Secretary of the Treasury. It is therefore suggested that the paragraph be changed to read as follows:

"SEC. 701 (a). The authority to promulgate such regulations as are specifically provided for by the terms of this act, except as otherwise provided in this section, is hereby vested in the Secretary."

The adoption of this amendment will exactly express the actual intention of the bill and prevent any uncertainty as to the meaning of the paragraph.

If any possible doubt is left as to its meaning, the fear that it may be claimed to confer a general power on the Secretary to make regulations on any subject or matter which might seem to him desirable, and whether expressly provided for or not, will render it unacceptable to many and give rise to opposition.

Dr. Craig and others have suggested amendments to sections 401 (a) 5 and 501 (e) with reference to coal tar color by which they seek to clarify the meaning by the insertion of the words "for the purpose of coloration" after the word "contains." The meaning of the sections, however, is apparently unambiguous, particularly when read in the light of the express language of sections 403 and 503, while the proposed amendment is so redundant and inept that it may have the effect of making uncertain what is now unmistakably clear. If, however, it is desired to amend the paragraph, the amendment should, in the interest of clarity, read as follows:

"Amend section 501 (e) by inserting in line 17 on page 21 after the word "contains" the words "for the purpose of coloring the cosmetic."

The paragraph will then read as follows:

"(e) If it contains, for the purpose of coloring the cosmetic, a coal tar color other than one from a batch that has been certified in accordance with regulations as provided by sections 503, 701 and 703."

In connection with the subject of idiosyncrasy or sensitivity, it was suggested, on the hearing, by others that specific provision be inserted to the effect that in construing and enforcing the section defining an adulterated drug, a reasonable allowance should be made for an allergic reaction to the use of a drug, and the same provision made with reference to the definition of an adulterated cosmetic. Another proposal was that when construing and enforcing the provisions of the act, reasonable allowances, consistent with the purposes of the act, should be made for abnormal individual reactions to foods, drugs and cosmetics. The chairman of the committee, however, expressed the thought that the matter would better be taken care of by a reference to it in the report of the committee.

It may well be that the necessity for considering allergic reaction in construing the provisions in question is so clear that no reference to it is required, either in the act or in the report, but, in the interest of clarity, and to avoid any possible doubt, it seems most desirable that the matter be taken care of through the adoption of one or the other of the methods proposed, and it is respectfully urged that this be done.

We desire to urge further that an amendment to section 711 (e) be adopted which will permit seizure actions to be removed to the district where claimant has its principal place of business and there tried as otherwise provided in the section. To accomplish this we suggest that the section be amended by striking out the words "where one of such seizures is pending which is nearest to the place of business of such claimant" as they appear in lines 7, 8, and 9 on page 45 and substituting in place thereof "where claimant has its principal place of business." This will take care of the suggestion that even with the language of the section as it is now drafted, the nearest district where one of the seizures is pending may still be two or three thousand miles away.

We also desire to endorse the suggestion that not more than one seizure action shall be instituted against any article of food, drug, or cosmetic if (1) the alleged violation is of misbranding or labelling only; (2) all current shipments of the article alleged to be misbranded bear the same labelling; and (3) such misbranding has

not been the basis of a prior judgment in favor of the United States in any criminal prosecution or libel for condemnation proceeding under the act; and provided further, that the single seizure action shall be instituted in or removed for trial to a distant district of reasonable proximity to the residence of the manufacturer, distributor, or claimant of the article seized. If this amendment is adopted, then it will be necessary to strike out the words "or misbranding" appearing in 711 (e) in lines 4 and 5 on page 45.

In the case of misbranding, it is no more than reasonable to ask the Government to establish the fact of misbranding by a judgment before seizures are made which may prove ruinous, particularly in view of the fact that the Government is entitled to an immediate and speedy trial of such a cause in preference to private cases. It further appears that multiple seizures in advance of a judgment are entirely unnecessary to insure a prompt enforcement of the law, since the Secretary is given, by the terms of section 712 (a) the right to obtain injunctions restraining the introduction into interstate commerce of any adulterated or misbranded food, drug, or cosmetic and he is given it for the very purpose of avoiding multiplicity of criminal prosecutions and libels.

We respectfully ask consideration for the foregoing suggestions.

Respectfully submitted.

CLARENCE N. GOODWIN,
Counsel for the Allied Manufacturers of the Beauty and Barber Industry.

Senator CLARK. Thank you. Mr. Mock.

STATEMENT OF HUGO MOCK, ASSOCIATED MANUFACTURERS OF TOILET ARTICLES OF NEW YORK, COMMITTEE OF THE TOILET GOODS INDUSTRY

Mr. MOCK. Mr. Chairman and gentlemen of the committee: I represent specifically the committee of the toilet-goods industry, which is composed of representatives of the Associated Manufacturers of Toilet Articles of New York, the cosmetic and perfume institute, the perfumery importers association, and association of manufacturers of cosmetic merchandise for syndicate stores and fixed-price stores, the Chicago Cosmetic Association, the California Cosmetic Association and others. I believe we represent substantially at least 95 percent of the industry.

At the outset I wish to make it clear that the committee of the toilet-goods industry is in favor of cosmetic legislation at this session of Congress. We are actively and affirmatively in favor of this legislation for several reasons.

This industry was left out of the food and drug act of 1906, but in the two decades that have passed since then the industry has developed to huge proportions. There was some suggestion at the time the previous bill was introduced into Congress that no cosmetic legislation was necessary. That may still be the case, but we feel that if the legislation governing cosmetics is definitive and constructive in character it cannot hurt us if we come under it, hence if we need regulation it is there.

We have another reason why we desire to see a bill of this character passed and that is that the regulation of cosmetics in some form is in the air. A number of bills less wisely drafted have been introduced into a number of States. We had an unfortunate experience in Maine last year, where a cosmetic bill was passed which its sponsors now admit was very unwise and of no use to the people of the State of Maine. Therefore we feel that if legislation is passed which will protect the public and honest cosmetic manufacturers, it will serve as a model bill for introduction into the several States of the United States.

I have here very few changes which I believe are necessary in the act, but before coming to these specific changes I wish to briefly discuss the question of advertising.

Some question has been raised here whether the control of advertising should be left with the Department of Agriculture or should revert to the Federal Trade Commission. We are strongly in favor of having advertising under the control of the agents of the Department of Agriculture, although they have had no experience specifically with cosmetics, we feel that their scientific training since 1906 has fitted them for this task. Where I represent a defendant I am very anxious to have the Federal Trade Commission handle the case, because I am well acquainted, and so is every lawyer here, with the snail-like workings of the Federal Trade Commission. It is well known that many cases have lingered in the Federal Trade Commission for 5 years and more before an order of dismissal or an order to cease and desist has been granted. The work of the Federal Trade Commission has been magnificent in other departments.

I make no criticism of it, because it was an original sort of commission. Its powers were very much hampered by its original constitution and it is not fitted to deal with these cases of misbranding and false advertising which require instant action. If a food, drug, or cosmetic is misbranded or falsely advertised, there is no reason in the world why any action against such advertising or misbranding should not be prompt, and in most cases I submit a policeman is more efficacious than a commission.

My principal objection to the wording of the bill itself is in the definition of the term "drug" on page 2, line 13, "all substances, preparations, and devices, other than food, intended to affect the structure or any function of the body." This definition should have the addition, "other than food or cosmetics", because under its present form it would include a number of substances which are properly considered as cosmetics, such as preparations for the hair, depilatories, deodorants, and so forth, all of which are intended to affect the structure or some function of the body.

In section 402, paragraph (k), it reads:

> If it purports to be or is represented as an inhibitory antiseptic for any use as a wet dressing, ointment, dressing powder,

And so forth.

Senator COPELAND. What was the reference?

Mr. MOCK. Page 19, paragraph (k), line 13.

Now, a well-known cosmetic is dusting powder. Babies are invariably, after they are bathed, dusted with an antiseptic dusting powder containing boric acid or a similar antiseptic. I think it is perfectly practical to state on the label of those cans, and the advertising of the same, that they have antiseptic qualities, and yet I have no idea that they will conform to the rigid test for antiseptics which is quite necessary for medical or surgical dressings. So I submit it would be only fair to the manufacturers of harmless dusting powders to insert there, after the word powder, "used for medical or surgical purposes."

Senator COPELAND. And then the powder that was used for ornamental or cosmetic purposes would go back to the cosmetic definition.

Mr. MOCK. Yes, Senator.

I haven't heard any mention today of a section of Mr. Dunn's bill, and the Mead bill, in which allergic reactions are provided for, and it is my suggestion that in section 501, paragraph (a), the words be added:

When construing and enforcing the provisions of this act reasonable allowances shall be made for abnormal individual reactions to cosmetics.

Senator COPELAND. I did not get that. Pardon me. What was the point?

Mr. MOCK. Allergy. I believe that it would be a constructive suggestion to add on page 21 to paragraph (a) of section 501 the words:

When construing and enforcing the provisions of this Act reasonable allowances shall be made for abnormal individual reactions to cosmetics.

Senator COPELAND. I think it is the intention to have in the report some reference made to the matter of allergy. We argued about it last year and did not get anywhere in the bill, and so we thought that in the report there might be some reference made to it, along the line you suggested.

Mr. MOCK. Thank you very much.

Section 502, with reference to marking cosmetics. I refer to page 22, paragraph (b). It refers to marking cosmetics by weight or measure. We are heartily in favor of that because the public is entitled to get what they are buying. There is in this section provided that reasonable variations shall be permitted—

And exemptions as to small packages and soap shall be established, by reguations prescribed by the Secretary.

We are inclined to go a little further than that an suggest that the exemptions be put in the bill itself. Under the laws of New York State, which has a similar labeling measure, and with which you are doubtless very well acquainted, liquid measure of 2 ounces or less is exempt, and by weight 3 ounces or less. I see no reason why the exemptions might not be stated in the bill itself, so that manufacturers could know exactly what objects they had to label.

There might, perhaps, be a further exemption made for fancy bottles, where it is difficult to estimate the contents, and especially where the labels would be marred by the inclusion of the weights or measures marking on the label.

I wish to endorse what Mr. Dunn said this morning about factory inspection. When this subject was originally brought up last year Dr. Campbell very properly introduced the instance of a case on the north shore of Maryland where crab meat was prepared and sent into interstate commerce, and it was quite necessary, in the interest of the public health, that that factory should be inspected and should come under the jurisdiction of this act. There is no such situation present in the manufacture of cosmetics. With perhaps a single exception I have never heard of unsanitary conditions in a cosmetic factory which might render the product at all dangerous to health. There is no more reason for the inspection of a cosmetic factory than there is for an inspection of a clothing factory, or an ax-handle factory, or any other factory, as far as the public health is concerned. I submit, as Mr. Dunn has suggested, there should be some, at least prima facie, presumption of the public health being affected or involved before there should be any public inspection of a cosmetic factory.

The many cosmetic manufacturers are highly jealous of their formulas. The bill, in its present form, gives very broad powers to anyone bearing the shield of an agent of the Department of Agriculture, and although it does provide penal provisions where that power is misused, if it is misused, the fact that the agent may be chucked in jail will be very small recompense to the manufacturer whose confidence has been betrayed.

Section 714, line 8, I think inadvertently something has come in there which should be corrected. It says:

If it appears from the examination of such samples or otherwise that any false advertisements of such article have been disseminated in the United States by the importer or exporter thereof, or any person—

then the goods shall be banned from interstate commerce.

Senator COPELAND. Excuse me just a minute. Mr. Campbell, will you listen to the argument on the point that is being raised by the witness?

Mr. MOCK. I wish to give you an actual instance. A highly regarded and scientific manufacturer of cosmetics has been sending his products from France into the United States for some time. A few weeks ago a purchaser, not the agent but a purchaser of this cosmetic, with a large establishment advertised that product falsely in a New York newspaper. It was a cream and it was advertised as a glandular preparation, which it was not. The mistake, or the crime, or whatever it was, was solely attributable to the importer of that product and not to the manufacturer. There are many other importers besides the specific importer who made the misleading statement. Now I submit it is altogether improper that the manufacturer in France should be penalized for a misstatement about a product of which he had no knowledge by a person not in any way in privity with him.

So I suggest that on page 49, line 8, the words "by the importer or exporter thereof" be changed to read "by the exporter or manufacturer thereof."

Senator COPELAND. Leaving out the word "importer."

Mr. MOCK. Leaving out the "importer."

I have just one more word to submit to the committee. The question of false advertising is a very vexing one. False advertising should be absolutely prohibited, whether it is a food or a cosmetic or a drug. The word "misleading" has, however, unless qualified in some way, a dangerous connotation, because the definition of the word "misleading" depends a great deal on the state of the mind of the person who reads it. A harmless talcum powder may be advertised as beneficial to the skin. Who is going to be the judge whether that is beneficial? An agent of the Department might consider that that was an exaggeration. These cases are constantly arising, so I believe there should be qualification of the word "misleading", such as is offered in the Mead bill, that harmless trade claims which are merely matters of opinion shall not be considered as a false or misleading advertisement. Thank you.

Senator CLARK. Dr. Fischelis.

STATEMENT OF ROBERT P. FISCHELIS, PRESIDENT AMERICAN PHARMACEUTICAL ASSOCIATION

Mr. FISCHELIS. I represent the American Pharmaceutical Association which is the professional association of pharmacists of the United States. The membership is open to all branches of the industry, as well as of the profession. I also represent the New Jersey Pharmaceutical Association, the New Jersey Board of Pharmacy, of which I am the secretary, and I also speak for myself in some of these matters.

The first point I would like to call the committee's attention to is the definition of the term "drug" on page 2, line 6, where the definition is qualified by the statement "and not for the regulation of the legalized practice of the healing art." We do not understand exactly what that means.

Senator COPELAND. If you will turn to page 3, line 17, you will see.

Mr. FISCHELIS. Yes, sir; but why omit, or why insert a qualification which might help to confuse the issue as far as drugs handled by physicians are concerned?

Senator COPELAND. That is, you would like to have it made clear that the pharmaceutical profession is included there?

Mr. FISCHELIS. No; I think the definition ought to read, "the term 'drug' for the purpose of this act includes" and then name what it includes, without the qualification that it does not include the regulation of the legalized practice of the healing art, because there may be some phases of drug regulation that are part of the healing art.

Senator COPELAND. We had great difficulty with that same paragraph because of the latter part of it. There was a fear on the part of some of the medical profession that it would interfere with the use of the devices that they use in medical offices. That was the reason that was inserted. I think there is a definite and very good reason for that in there.

Mr. FISCHELIS. Yes, sir. I would like to call it to your attention at any rate.

On page 14, lines 10 to 18, which read:

> No drug shall be deemed to be adulterated under this paragraph because it, differs from the standards of strength, quality, or purity therefor set forth in an official compendium, if its label bears in juxtaposition with the name of the drug a statement indicating wherein its strength, quality, and purity, as determined by the tests or methods of assay, applicable under this paragraph, differ from the methods therefor set forth in such compendium.

We think that should be omitted.

Senator COPELAND. If you find a way to cover a variation we will give you a medal. We worked for days over it. Dr. Beal reached the conclusion that this language, as we have it, including the previous part of it, is the most satisfactory we can find. If you find a better way, however, we will be mighty glad to have it.

Mr. FISCHELIS. Our association is on record emphatically protesting against the use of U. S. P. and N. F. titles for any preparations except those which are prepared exactly according to U. S. P. and N. F. formulas. The pharmacopœia has been developed in order to standardize medicines so a prescription written in Maine can be filled in California and be filled exactly in the same way. If an official title is used it should conform to an official standard. Nomenclature is one of the basic factors in standardization. If you have a definite

name which means one thing in one place and another thing some place else, or if someone is allowed to use an official title without complying with the official standards, you are breaking down the standards that you have set up.

Senator COPELAND. We would meet that objection by striking out beginning with line 10?

Mr. FISCHELIS. By striking out beginning with the word "no" and ending on line 18 with the word "compendium".

Senator COPELAND. That is, strike out that sentence?

Mr. FISCHELIS. Yes, sir.

On page 16, line 24, we believe that the words "names and quantity or proportion" should be retained.

Senator COPELAND. What page?

Mr. FISCHELIS. Page 16, line 24. You have stricken out "names and quantity or proportion"; we believe it should be retained, so that the names and quantity or proportion of ingredients are mentioned on the label. Now, the manufacturers of prescription products have given their formulas on labels for years. There are, of course, some exceptions, and principally in connection with those products which were first marketed to the medical profession and then later became "patent medicines," because they were transferred to general public use. The disclosure of the actual ingredients and quantities of a formula should be compulsory, first, in the interests of intelligent self-medication. A layman cannot medicate himself intelligently if he wishes to, if he is not cognizant of the constituents of the medicine. He may have been informed that he has an allergy or idiosyncrasy toward a certain drug. If he does not know that that drug is contained in the preparation it is dangerous to his health to use it.

Senator COPELAND. We tried to cover that by including, as we have here, the name of each active ingredient, so if he knew that he had an alleged reaction to some drug he would be protected against it. But you think we haven't gone far enough.

Mr. FISCHELIS. Exactly. Furthermore, it is necessary to have the formula disclosed in order to warn against harmful, toxic and otherwise deleterious ingredients, to enable intelligent dosage and avoid the danger of habit formation, to protect the public against remedies which are not properly prepared and to compel honest advertising. An advertiser's statements will fall flat if they are not borne out by the therapeutic activity of every ingredient which is given on his label. So the disclosure of the formular would help to bring about honest advertising.

Furthermore, a stock formula product may be changed in its formula any time without notice to anybody, whereas the compulsion to disclose the formula gives notice at once to the medical profession, to the public and other users of the product that there has been a change, which is only fair to the consumer.

As far as any effect on the industry is concerned, it is quite well known that a new and useful remedy, chemical substance or other composition may be patented, that all preparations may be trade marked if the manufacturer desires to retain exclusive right to a product, and, of course, the manufacturer also has his advertising as a basis for protection even if the formula is disclosed.

The American Pharmaceutical Association is on record on this matter. It stated, as far back as 1927, that it—

> Favors legislation looking toward a partial formula disclosure of proprietary medicines, sufficient to show their content of potent ingredients, without in any manner infringing on the property rights of the manufacturer or proprietor; and that distribution to the public be properly safeguarded.

It was the consensus of opinion at the time this resolution was passed that there should not be disclosure of special manufacturing practices or of special ingredients used for flavoring or to increase palatability or appearance, but the active therapeutic ingredients should be revealed, both in name and in quantity.

I would like to call the attention of the committee to a survey of the drug industry made by the committee on the costs of medical care a few years ago and I would like to put into the record a reference from a part of this survey. The reference is:

> It is incongruous that the medical profession should be constrained by professional and public opinion to follow rigorous codes of ethics in the advertising of their services, whereas the manufacturers and distributors of medicines—who are to a certain degree in economic competition with medical practitioners and institutions—should utilize the merchandising methods of ordinary business enterprise. Advertisements of "patent medicines" are inappropriate media for the diagnosis of, or recommendation of treatment for, a patient's condition. The buyer of "patent medicines" purchases an article, the composition of which is secret and the action of which he does not fully understand, to serve a need, which he does not ordinarily comprehend.
>
> Federal and State laws governing the manufacture and distribution of drugs and medicines are inadequate. Legally, anybody can manufacture medicines, regardless of ability, skill, training, equipment, or knowledge of the dangers involved. At the present time, formulas of medicines need not be disclosed, and medicines need not be labeled unless they contain certain proscribed drugs or poisons. Regulations governing the pharmacal profession and the practice of pharmacy by pharmacists are very strict, but the privileges of unlicensed persons operating outside of pharmacies are so extensive that the public enjoys little protection in the matter of sales of packaged medicines.
>
> Under ordinary circumstances, the control exercised by the professions of medicine, pharmacy, and dentistry through their respective educational activities have a more far-reaching effect in many ways than legislative enactments. The hope for better public control of the medicine industry lies in the direction of an enlightened public opinion brought about by educational efforts. Legislation which will follow such effort is more apt to ignore the selfish interests of promoters and to consider the public welfare as well as the public's pocket book.

Now, in connection with that statement I would like to recommend the inclusion of a provision for the licensing of manufacturers. This is in the interest of the decent manufacturer of medicines, as well as the public interest, because there has been a multiplicity of fly-by-night concerns which have flooded the market with various types of remedies of questionable value. The pharmacists, physicians, and dentists are licensed to practice their profession, and the manufacture of drugs and medicines is a function which ought to require some type of Government control. Every retail drug store must have a licensed pharmacist to operate it, and many pharmacies in our different States must have licenses in order to operate. It seems entirely fair, under the circumstances, that manufacturers of drug products should likewise be compelled to obtain licenses to operate, upon the fulfillment of satisfactory conditions with regard to competency of personnel, equipment, and sanitary surroundings, and standardization of finished products. Enforcement of the law will be greatly simplified if all manufacturers are compelled to operate under Government license.

On the matter of control of advertising we feel that in dealing with drugs and medicines you are not dealing with ordinary commodities of trade. Therefore, the Federal Trade Commission, which is primarily concerned with trade and the regulation of trade, and competition is not the proper body to regulate the manufacture, advertising, or distribution of drugs and medicines. The United States Department of Agriculture, through the Food and Drug Administration, in the last 29 years has given sufficient evidence of its reasonableness in enforcement procedures. It has shown a due regard for the public interest, as well as for the interests of those who are engaged in selling the public, and therefore, we feel that it is the proper department to continue to supervise all phases of food and drug regulation, including advertising.

There are two more things in the bill itself which I would like to call your attention to. Section 501, page 21, subsection (b), we think should be retained instead of stricken out. The same is true of section 503, page 23, subsection (a).

Senator COPELAND. Just a moment. I will make a note of this.

Mr. FISCHELIS. Page 21, section (b), lines 4 to 7.

Senator COPELAND. And where is the other one?

Mr. FISCHELIS. Section 503, page 23, subsection (a). It is advisable to prescribe limits of toxic substances and poisons used in the preparations in quantities that may not be injurious to health. Some may be injurious to health and others may be injurious in certain quantities. Therefore, it seems that a limit should be prescribed and prohibitions are necessary.

In the matter of the regulations as to prosecution, we feel again that the Food and Drug Administration has amply demonstrated its fairness in prosecutions and any request coming from that administration for more extensive enforcement measures should be given very careful consideration, and as far as we are concerned, approval.

Thank you.

Senator COPELAND. Thank you very much. The committee will adjourn until Friday at 10 o'clock.

(Whereupon, at 4:45 p. m., the committee adjourned until Friday, Mar. 8, 1935, at 10 a. m.)

FOODS, DRUGS, AND COSMETICS

FRIDAY, MARCH 8, 1935

UNITED STATES SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to adjournment, in the caucus room, Senate Office Building, at 10 a. m., to further consider S. 5, Senator Clark, chairman of the subcommittee, presiding.

Present: Senators Clark (chairman), Copeland, and Gibson.

Senator CLARK. The committee will come to order.

Senator Austin, do you desire to make a statement?

STATEMENT OF HON. WARREN R. AUSTIN, A UNITED STATES SENATOR FROM THE STATE OF VERMONT

Senator AUSTIN. Mr. Chairman and gentlemen of the committee, I present for your consideration and would like to have printed in your record of this hearing, the following resolution and letter of the Vermont State Farm Bureau, dated respectively January 16, 1935, and January 26, 1935; a letter of C. W. Crawford, acting chief of the Food and Drug Administration, United States Department of Agriculture, dated Febrary 18, 1935; a letter of the American Farm Bureau Federation, dated February 19, 1935; a letter of Hon. Guy W. Bailey president of the University of Vermont, dated March 6, 1935; a letter of J. E. Carrigan, director of cooperative extension work in agriculture and home economics, State of Vermont, the same date; a letter of Dr. J. L. Hills, director of the Vermont Agricultural Experiment Station of the same date; a letter of A. H. Packard, president of the Vermont Farm Bureau, the same date, and a letter of Linus Ward, manager of the Vermont Maple Cooperative, Inc., the same date. These all bear upon the food provisions of the bill.

(The resolution and letters referred to are as follows:)

VERMONT STATE FARM BUREAU,
Burlington, Vt., January 26, 1935.

Senator WARREN R. AUSTIN,
Washington, D. C.

DEAR SIR: At the annual meeting of the Maple Sugar Makers Association held at Burlington last week, certain resolutions were passed which the members felt reflected the immediate needs of the maple industry.

One of these resolutions refers to the abuses of packing decolorized maple sirup and using a label stating it is pure maple sirup. The Federal Pure Food Act will need amending to correct this.

I am enclosing a copy of the resolution and I am sure the president and secretary of the association would appreciate a word from you concerning the subject.

The name of the president of the association is George Hathorn and his address is White River Junction, Vt. The name of the secretary is Ray Collins and address is Colchester.

Most respectfully yours,

A. H. PACKARD, *President.*

RESOLUTION

At a meeting held on January 16, 1935, of the Vermont Maple Sugar Makers Association the following resolution was adopted:

"*Resolved*, That the Vermont Senators and Representatives in Washington cooperate with this association to have the Federal Pure Food Department amend the present law and regulations on sirup, which will make it compulsory for all packers who decolorize sirup to mark on the packages that the contents of the packages have been decolorized and making it an offense not to comply with this regulation.

DEPARTMENT OF AGRICULTURE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., February 18, 1935.

Hon. WARREN R. AUSTIN,
United States Senate, Washington, D.C.

DEAR SENATOR: I have your letter of February 15 with enclosures concerning the applicability of the pending bill for revision of the Federal Food and Drugs Act, S. 5, to the decolorizing of maple sirup and the false advertising of that product.

I have read very carefully Commissioner Jones' letter of February 13 in which, after study of S. 5, he expresses some doubt that it will effectively control the situation he describes.

From my own consideration of the problem and the provisions of S. 5, I am forced to the conclusion that the absuses complained of could be corrected by the enactment of this bill.

It seems certain that the decolorizing of maple sirup changes the identity of the product through the abstraction of natural coloring constituents. Therefore, a definition and standard of identity could be set up under paragraph (g) of section 302 defining decolorized maple sirup. You will note that this paragraph also defines the food as misbranded if its label fails to carry the name of the food prescribed in the definition and standard. In such circumstances a decolorized product would be required to be labeled with the defined name, that is, decolorized maple sirup. If it were sold simply as maple sirup, then it would violate not only this provision but paragraphs (a) and (b) of the same section in that its label is false and that it is offered for sale under the name of another food. It would also violate section 301 (b) (3) in that its inferiority had been concealed if, as I understand from Commissioner Jones' statement, the sirup to which this process is applied is definitely inferior to normal sirup.

Referring to the question of false advertising, let me point out that section 601 defines an advertisement as false, if it is false or misleading in any particular. This language is included in the misbranding provisions of the present law. The following is a quotation from a Supreme Court decision interpreting that language:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. The statute applies to food, and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is." (265 U. S. 438.)

I believe that these provisions of the bill and perhaps others may be brought to bear to accomplish fully the correction of the evils in question.

If I can be of any further service, please do not hesitate to let me know.

Very truly yours,

C. W. CRAWFORD, *Acting Chief.*

AMERICAN FARM BUREAU FEDERATION,
Washington, D. C., February 19, 1935.

Senator WARREN R. AUSTIN,
Senate Office Building, Washington, D. C.

MY DEAR SENATOR AUSTIN: I appreciate greatly having your letter of February 18, with attachments, all bearing upon the question of proper labeling protection of the pure Vermont maple sirup products.

I have discussed this matter at different times with President Packard. I shall be interested in knowing through your office whether or not Mr. Crawford, of the Pure Food and Drug Administration, considers that S. 5, now pending, properly takes care of the Vermont situation, or if not, what amendment we might stand for which would cover the situation.

I have told President Packard that, in my judgment, the way to handle this situation is in connection with whatever amendments are adopted to the Pure Food and Drug Administration. It would be difficult to the point of being impossible to get a special bill through on this subject, in my judgment.

Very respectfully,

CHESTER H. GRAY,
Washington Representative.

THE UNIVERSITY OF VERMONT,
Burlington, Vt., March 6, 1935.

Hon. WARREN R. AUSTIN,
United States Senate, Washington, D. C.

MY DEAR SENATOR AUSTIN: May I point out that while, in my judgment, much has been accomplished since the enactment of the present Federal Food and Drug Act, much more could be accomplished if the Copeland bill (S. 5) were to be enacted to replace it. This would be a long stride in advance.

I sincerely hope it may be enacted into law not only because of its general effect upon the public welfare, but because there is a crying need of relief in respect to the sale of pure maple sirup, Vermont's most distinctive food product. This is now subjected to serious competition with decolorized, yet pure goods. I believe that this, as well as any other undesirable situations, might be cleared up were the Copeland bill made a law.

Yours very truly,

GUY W. BAILEY, *President.*

COOPERATIVE EXTENSION WORK IN AGRICULTURE AND
HOME ECONOMICS, STATE OF VERMONT,
March 6, 1935.

Hon. WARREN R. AUSTIN,
United States Senate, Washington, D. C.

DEAR SENATOR AUSTIN: I am glad to note your interest in Senate bill 5 and its relation to the maple industry of Vermont. I believe you already know that decolorized maple sirup of low grade is oftentimes sold in competition with high-grade maple sirup. The decolorization gives it the appearance of being the same quality product as that with which it is competing. The maple producers of Vermont, as I have contacted them, have over and over again expressed to me their conviction that such decolorized product when sold should have the fact that it is bleached or decolorized plainly marked on the label, and also that when it is advertised that the advertisement carry the same information.

It seems to me that Senate bill 5 will provide legislation whereby it may be possible to protect the high-grade product from unfair competition with the decolorized low-grade product. And I believe that the maple producers of Vermont are a unit in desiring that such legislation be provided. I hope it may be possible to make this clear before the Senate committee, which is, I understand, holding hearings on Senate bill 5 this week.

Your very truly,

J. E. CARRIGAN, *Director.*

VERMONT AGRICULTURAL EXPERIMENT STATION,
Burlington, Vt., March 6, 1935.

Hon. WARREN R. AUSTIN,
United States Senate Building, Washington, D. C.

MY DEAR SENATOR AUSTIN: I most sincerely trust that the Copeland bill (S. 5) may be made law.

It was my privilege to know somewhat intimately Dr. Harvey W. Wiley, the father of Federal pure food and drug legislation. I know how long, how earnestly, how effectively he labored in its interests. I feel sure, were he alive, that he would be heart and soul for the Copeland bill.

I plead for its enactment not only on general grounds, but also for a very specific reason. Vermont's most characteristic food product is born of the maple tree. Pure Vermont maple sirup is now meeting an insidious and dangerous type of competition due to the decolorization of the low grades. If the Copeland bill should become law, such goods might become unmasked, and then they would have to sell for what they are.

Yours truly,

J. L. HILLS, *Director.*

VERMONT STATE FARM BUREAU,
Burlington, Vt., March 6, 1935.

Senator WARREN R. AUSTIN,

MY DEAR SENATOR: It is my understanding that a bill is now before the United States Senate, S. 5, which if passed would prevent misbranding of food products.

In this State several years ago certain standards were set up by the Department of Agriculture for grading maple syrup. These standards are Fancy (U. S. color no. 5 or better), No. 1 (U. S. color no. 7 to no. 5), No. 2 (U. S. color no. 9 to no. 7).

As a result of this, producers now have adopted better practices and use better evaporators in order to produce high-grade syrup. All this costs extra money.

Now, we find certain syrup dealers purchasing low-grade syrup and by using certain preparations remove the dark color, thereby producing a syrup amber in color. This although sadly lacking in flavor is labeled and sold as pure.

As a result all the efforts of producers of Vermont and nearby States to make high-quality syrup is largely thrown into the discard.

The producers of maple syrup in Vermont want protection from this decolorized product and they desire the passage of legislation S. 5 at an early date.

This practice of decolorization may turn profit to the few who indulge in it, but is grossly unfair to those who consume it and a great injustice to thousands of maple-syrup producers.

Most respectfully yours,

A. H. PACKARD, *President.*

VERMONT MAPLE COOPERATIVE, INC.,
Essex Junction, Vt., March 6, 1935.

Senator WARREN R. AUSTIN,
United States Senate, Washington, D. C.

DEAR SENATOR AUSTIN: On behalf of the Vermont Maple Cooperative, Ind., I hereby advise you that the association desires to go on record as favoring the passage of Senate Bill no. 5, so-called the "Copeland bill."

We believe that the passage of this bill will be of benefit to the marketing of maple syrup as a pure food, and urge your support of it.

One of the principal needs of the maple industry in Vermont is to secure protection against the decolorizing of maple syrup.

Cordially yours,

LINUS WARD, *Manager.*

Senator AUSTIN. I also would like to have printed in the record the text of an advertisement which I submit, by Vermont Maid Syrup, and in connection with this one brief paragraph in the retiring message of Hon. Stanley C. Wilson, Governor of the State of Vermont, to the General Assembly, dated January 10, 1935, entitled "Maple Syrup and Unfair Competition."

(The advertisement and brief paragraph referred to are as follows:)

"I can taste that flavor of real Vermont maple sugar."

From the world's maple-sugar "headquarters" comes this delicious blend of cane and maple sugars.

Do you remember long ago when your Aunt Ida sent you that delicious maple sugar from Vermont?

Well, up here—in the heart of the famous maple country—Vermont Maid Syrup is blended for your table.

Pure maple sugar—from a choice selection of Vermont's maple crop—is skillfully blended with pure cane sugar to bring out that rich maple tang.

Tomorrow morning, give your family a surprise. Make a batch of delicate brown pancakes or tender waffles.

Just imagine them with a dab of butter floating in a golden pool of rich Vermont Maid Syrup. Umm! It makes you hungry just to read about it.

Remember the name—Vermont Maid Syrup. It's the finest syrup you can buy. Penick & Ford, Ltd., Inc., Burlington, Vt.—Vermont Maid Syrup.

MAPLE SIRUP AND UNFAIR COMPETITION

Vermont is famous for her maple sirup and sugar. Because Vermont maple products are recognized as leading in quality, certain manufacturers of blend sirups are now putting them on the market under names and in connection with advertising apparently cleverly designed to deceive consumers into the belief that they are really the product of the maple forests of Vermont. Some of these blend sirups contain but little maple product and even that is understood to be largely imported. Whether or not this practice is actionable under Federal laws, I believe Vermont has the power to protect its maple-sugar makers from this unfair competition to some extent. I suggest that the manufacture, labeling, sale, and advertising of such products within this State are within the control of the State and that carefully drawn legislation should be enacted to curb these practices that are greatly injuring our farmers. I am for Vermont made sirup spelled M-A-D-E.

Senator CLARK. The exhibits presented to the Senate will be received and printed.

Senator COPELAND. Just one moment. Senator, what you desire is that nothing should be put in this bill that would prevent the establishment of standards of quality for nationally sold maple-sirup products?

Senator AUSTIN. That is correct.

Senator COPELAND. If this bill were changed to read as it did last year, "That no standard shall be established for fresh fruits and fresh vegetables" that would meet with your approval?

Senator AUSTIN. Yes; if it were left as the bill was drafted to refer to natural—what is the word "natural"?

Senator COPELAND. Natural food.

Senator AUSTIN. Natural food or foods.

I have ascertained that there might be such ambiguity in those words as to exclude maple sirup and possibly dairy products.

Senator CLARK. We will now hear from Judge Davis. Judge, there has been some controversy in these hearings as to the question of whether or not the pending measure in a sense transferring jurisdiction of advertising from the Federal Trade Commission to the Department of Agriculture would in fact infringe on the present jurisdiction of the Federal Trade Commission, and it was for this reason I asked the Commission to have a representative here today for the purpose of making any statement that the Federal Trade Commission might desire to make in regard to the bill.

STATEMENT OF HON. EWIN L. DAVIS, CHAIRMAN OF THE FEDERAL TRADE COMMISSION

Mr. DAVIS. Mr. Chairman and other gentlemen of the Committee: I wish to state that the Commission appreciates the desire of the Committee to hear a representative of the Commission with regard to the matter mentioned.

The bill under consideration does infringe upon the jurisdiction of the Federal Trade Commission which it has had and exercised for 20 years.

As to the unfair methods of competition in commerce that are declared to be unlawful, the Federal Trade Commission is empowered and directed to prevent such practices. Under that the courts have uniformly and repeatedly held that false or misleading advertising came within the purview of that provision of the law, and the Commission has handled thousands and thousands of advertising cases of every character.

The jurisdiction of the Commission covers all forms of advertising of all commodities, and of the reported cases about 70 percent of what we call the section 5 cases, or unfair method of competition cases, handled by the Commission, constituted some form of false, misleading advertising, and of this number, about 20 per cent related to false or misleading advertising of food, drugs and cosmetics, the other 80 percent of the advertising cases relating to other commodities.

The Commission handles these cases in what might be regarded as two methods. We have a Chief Examiner's Division, to whom is referred all complaints which may be received from individuals, consumers, competitors, Better Business Bureaus, trade organizations, or from any source. They are referred to him for investigation, and may require an investigation by one of our field representatives. And the concern advertising the commodity is always contacted and given an opportunity to state its position and any defense it may have. If the preliminary investigation indicates to the Commission that there is probably a violation of the law, and if the case does not involve a clear case of fraud, or an old offender, or certain violations of the Clayton Act, the proposed respondent is given an opportunity to adjust the matter by stipulation by signing an agreement that it will cease and desist from the practices condemned and not resume them in the future. A large percentage of our cases, in fact an overwhelming percentage of our cases, are settled in that manner, without the issuance of a formal complaint, and without the necessity or the expense both to the Government and the proposed respondent of a trial.

However, if the proposed respondent declines to sign a stipulation, if he insists that hs is not misrepresenting his commodity, or its value, or anything in relation to it, and he wants to try his rights, the Commission issues a formal complaint reciting the charges. It is served upon him and he has 20 days within which to file answer. Then it is referred to a trial examiner, who up until this time has had nothing to do with the case, and who sits there in an impartial capacity, and first an attorney for the Commission introduces proof, and the attorney for the other side has the right of cross-examination. Then when the Commission's proof is concluded, the respondent introduces his proof, of course counsel for the Commission having the right to cross-examine his witnesses. When the evidence is concluded the trial examiner declares a finding of facts to which either side may except. Then when that is done, both sides file a brief, and if it is desired, the entire Commission grants an oral hearing before the case is finally decided, and then it is heard by the Commission. Then if the Commission issues a cease and desist order, that ends it, unless the respondent is still dissatisfied and desires to appeal. And he has

the right of appeal to the United States Circuit Court of Appeals. If he perfects his appeal, under the F. T. C. statute the Court of Appeals shall give priority over these cases, and they are expedited. When it is decided by the Circuit Court of Appeals, of course, it may go on certiorari to the Supreme Court just as any other case.

Another method by which we handle advertising cases is where they are handled initially by a special board of investigation, which the Commission set up a few years ago in order to expedite the handling of this character of cases, and it is composed of three lawyers. They scan advertising, looking for what may appear to be false advertising. They have scanned at the rate of about 20,000 periodicals per annum, and during the past 4 years, in that way they have listed 1,493 periodical advertisements as apparent violations and requiring further investigation, and of that number, 844 came in and after discussion and consideration, personally or through counsel, or both, signed stipulations agreeing to cease and desist. It was necessary to issue only 33 complaints out of that number.

In that connection, I want to state to you gentlemen that we have had a rather peculiar experience in a way, as on first blush we would naturally assume that a respondent would be less likely to violate a cease and desist order than he would a stipulation, but our experience has been the other way. The chief trial examiner reported to the Commission the other day that of the last 1,800 stipulations signed by both the Commission and the respondents, which had been prepared by his division, there had only been one violation which the Commission learned of and which it directed procedure against, and that was not a violation of a specific, literal feature of the stipulation, but was the employment of a substitute, which the Commission thought was practically the same thing.

Another matter I wish to bring to your attention is this: That up until last year, the Commission had not handled radio advertisements except when complaints came to it. There was not any question about the Commission having jurisdiction over radio advertising just like any other misrepresentation, but it was new, and they had received much less complaint because it is much easier for some one interested to send in a newspaper and call attention to an advertisement than it is to undertake to recite what somebody said over the radio. Furthermore, it involved a difficult problem for the Commission itself within its means to undertake to assume a surveillance over the innumerable programs going over the air every day and night. But last spring the Commission decided to definitely give that matter the same character of attention that it had heretofore given to other forms of advertising. And after several conferences with the radio executives, including some of the officials of the National Association of Broadcasters, the Commission worked out a plan by which it was agreed that we would call upon all of the broadcasting stations, approximately 600 in number, and all of the chain systems and the transcription companies to furnish the Commission with duplicate copies of the advertising, or continuities, as they call them. We did not care for the entertainment programs, but simply the portions of the programs which related to advertising, or some effort to sell something to the public. They readily approved that plan, and so we made the first call effective July 1, for the month of July, and during the month of July the radio stations responded 100 percent,

the chain stations responded 100 percent, and all the transcription companies except a very few which were apparently at the time doing no business. We received all told during July, about 183,000 different radio advertisements.

The procedure employed then is what has been since pursued, and that is that these were scanned. Those that were clearly unobjectionable were filed. Those that were clearly objectionable, of course, went to the board primarily for consideration, and those that were of a doubtful nature were handled separately. All of those that were not passed as being all right were given further attention, and generally a questionnaire was sent to the advertiser, and perhaps he was called on for a sample, or his formula, and various other data. And when that was received, it might be that the Commission would want some test made, either by the Food and Drug Administration, or by the Bureau of Standards, or the Public Health Service, or somebody else. Then if it developed that there was probably a violation of the law, the special board makes a recommendation to the Commission for stipulation or complaint. It is generally a stipulation, failing which a complaint, if they think there is a violation of the law, and if the Commission confirms it we proceed just like I explained before in a case coming from the Chief Examiner's Division. If it is settled by stipulation, of course that ends it. If the proposed respondent wants to, he is permitted to come in and discuss the matter, present his claims and adjust it.

Sometimes it will be that he is not willing to sign the stipulation, just as first prepared. He will say, "I think this is exacting too much of me, because I do not think it is within the facts"; and finally if it is not adjusted by stipulation and the Commission feels there is a law violation, it issues a complaint and proceeds as I have heretofore indicated.

Gentlemen, to give you some conception of how much work is being done along the advertising line——

Senator COPELAND (interposing). May I interrupt?

Mr. DAVIS. Certainly.

Senator COPELAND. I wish to interrupt you to say that I think the Federal Trade Commission has rendered a great public service in what it has done in the control of the false advertising and unfair practice, and so far as I am concerned, I concede that at once.

My thought about this is that this bill in no sense seeks to restrict the normal operations of the Federal Trade Commission. This has to do wholly with those matters which relate directly to what might be called the extension of the label in the advertising of foods and drugs. So far as the economic features and the control of unfair practices in the normal operation of this able Bureau, so far as they are concerned, there is no disposition on the part of this committee, I assure you, to change the practices as they exist at present.

Mr. DAVIS. Senator Copeland, we appreciate that friendly expression very much.

I want to state, as I interpret the bill, it does not specifically deprive the Federal Trade Commission of jurisdiction, but it places the Food and Drug Administration in exactly the same field, and duplicates the authority and work of the Federal Trade Commission with respect to advertising of food, drugs, and cosmetics.

Senator COPELAND. No, Judge, I do not agree with you. So far as those things having to do with the public health and the immediate control of the consumer and the citizen, there is a greater power given here than has been theretofore. I mean that as to the Food and Drug Administration, so far as all these things having to do with fair practices and the economic features of the work, those things which have been so well done by your Commission, there is no disposition to make any change whatever; and for myself, speaking only as one member, I am perfectly willing to have the report on this bill indicate that that is the spirit of the committee.

Mr. DAVIS. Now, I wish to again reiterate in behalf of the Commission that we appreciate that attitude, but, Senator Copeland and other gentlemen of the committee, if it is to be so restricted, then I respectfully submit the bill would have to be amended. And in the second place, as the courts have said, false advertising is an unfair method of competition, it is an unfair trade practice, whether the purpose is to sell drugs, cosmetics, furniture, or clothing, or what not. It is a commercial proposition. It is a trade proposition. They advertise it for the purpose of promoting a sale. Now, it is an unfair trade practice.

Senator COPELAND. It goes further than that, Judge. I have heard repeatedly advertising over the radio of a certain drug, with a statement made that "in no instance has any harm been received from the use of this, it is a harmless thing, it may be safely taken," and so forth. That is not a matter that you could deal with. That is a matter that has to do with the medical side of the thing, and evidence would have to be brought on the medical side to show whether that statement was true or not. That has nothing to do with unfair practices or the economic control of the advertising.

Mr. DAVIS. Senator, I do not think you could mathematically draw any line of demarcation between the character of medicines in which they simply state overexaggeration of therapeutic value, or the number or character of diseases for which they would be beneficial. As to whether a drug is not harmful or one the improper use of which would be injurious is a controversy in almost every case that you cannot determine until you get into it. That is generally a development of the case.

Senator CLARK. Judge, a suggestion has been made here in previous hearings that necessarily the Federal Trade Commission did not have a scientific and technical staff for the purpose of determining such questions as you have just mentioned, and that by the very nature and institution of the Food and Drug Administration in the Agriculture Department that they do have such a technical staff, which renders them peculiarly able to investigate such matters and to take action without unnecessary and cumbersome delay. I would be very glad to hear your expression on that subject.

Mr. DAVIS. Senator, I shall be very glad to do that. In reply to that, I say that the Food and Drug Administration has some chemists and doctors and a laboratory to make tests. The Federal Trade Commission could equally establish the same if it desired; but rather than do that we have called upon the Food and Drug Administration to make analyses, to make reports, and to make tests for us in cases in which they could render the best service, the Public Health Service as to others, and the Bureau of Standards with respect to

others. Because the Bureau of Standards is better equipped than any organization in America to make a certain character of tests, certainly it is no argument why it should be given jurisdiction over commodities of that character, but there is just as much reason for that as to argue that the Food and Drug Administration should be given jurisdiction over the whole field of investigation because they happen to have some scientific men to make the tests.

So far as the other feature of it is concerned, we respectfully submit that the Federal Trade Commission is infinitely better equipped to make field investigations. We have a force of trained lawyers, economists, accountants, and men in each class who have devoted years and years to a particular line of study in industry. We have branch offices. We are sending men out at Government expense to make these investigations and to develop these facts. And to simply deprive us of a portion of that jurisdiction and place it somewhere else, would make it necessary for the Food and Drug Administration to set up a comparable organization to make those field investigations.

If you will permit it, I should like to answer the question in the words of the United States Supreme Court in a recent decision. I read an excerpt from the opinion of the United States Supreme Court affirming the Commission's cease and desist order, entered against R. F. Keppel & Bro., Inc. *Federal Trade Commission* v. *R. F. Keppel & Brother, Inc.* (291 U. S. 304):

> While this Court has declared that it is for the courts to determine what practices or methods of competition are to be deemed unfair, *Federal Trade Commission* v. *Gratz*, supra, in passing on that question the determination of the Commission is of weight. It was created with the avowed purpose of lodging the administrative functions committed to it in "a body specially competent to deal with them by reason of information, experience, and careful study of the business and economic conditions of the industry affected", and it was organized in such a manner, with respect to the length and expiration of the terms of office of its members, as would "give to them an opportunity to acquire the expertness in dealing with these special questions concerning industry that comes from experience." (Report of Senate Committee on Interstate Commerce, No. 597, June 13, 1914, 63d Cong., 2d sess., pp. 9, 11; see *Federal Trade Commission* v. *Beechnut Packing Co.*, supra, at 453; compare *Illinois Central R. R.* v. *Interstate Commerce Commission* (206 U. S. 441, 454).) If the point were more doubtful than we think it, we should hestiate to reject the conclusion of the Commission, based as it is upon clear, specific, and comprehensive findings supported by evidence.

In that connection, if I may, I should like to have inserted at the end of my statement some extracts from other Supreme Court decisions.

Senator CLARK. That may be done.

Mr. DAVIS. I want the committee to understand this, that we are not appearing here in any hostile attitude to the purpose which you have in mind to protect the public health. We have been doing our best to do the same thing. We think that the records show that the Commission has a splendid record.

Senator COPELAND. I want to underwrite that statement.

Mr. DAVIS. Thank you. It has handled thousands and thousands of cases, and has been reversed in a very small percentage, and the fact of the business is that the vast majority have been adjusted satisfactorily and effectively, both to the Government and the member of the industry without resorting to expensive and wearisome legislation; and we of course have encountered some difficulties as has the Food and Drug Administration growing out of certain restricted rulings and interpretations by the Suprene Court, but with some very

simple moderate amendments to section 5 and the procedural features of our act, much less substantial than proposed amendments or changes in the Food and Drug Administration, this Commission would be able to proceed with greater efficiency and greater expedition and more economy.

If it is developed, as has been suggested, that some of the decisions have hampered the Federal Trade Commission, we respectfully suggest consideration of amending the Federal Trade Commission Act, instead of depriving them of a jurisdiction in order to give it to another agency, for which an entirely new bill has to be written.

I want to state that our relations with the Food and Drug Administration and various other departments of the Government have been entirely cordial. They have repeatedly referred advertising cases to us. We have repeatedly called upon them for analyses and opinions.

As to whether the practice which has obtained should be changed, of course, is a matter for you gentlemen and all the Congress, and of course we will cheerfully abide by whatever you do, but if I may proceed just one thought further before concluding, right along the line of the interest of Senator Copeland in the public health, with which I am in full accord, you may leave advertising out of the plan entirely so far as the Food and Drug Administration is concerned.

The Food and Drug Administration under the provisions of this bill and in large measure under the present law has the right to seize, has the right to destroy impure, poisonous, and harmful drugs and foods. They have a right to stop the sale of it. They have a right to absolutely suppress it, in other words. If it comes within the character that it is harmful to the public health they have a right to suppress it. If they do suppress it there is no occasion for any further advertising or handling advertising. But if it comes within the class that is not impure, is not poisonous, is not injurious to the public health, but simply involving extravagant claims with respect to its value, therapeutic value or other value, so that the advertising cannot be stopped because the Food and Drug Administration perhaps cannot suppress the sale of it simply for misrepresentations of its value. They cannot suppress it. They cannot condemn it. But then the Federal Trade Commission can step in, as it has so many times done, and stop these extravagant advertising claims. In other words, the way it has been there has been no real conflict. Wherever the Food and Drug Administration has assumed jurisdiction over a poisonous drug, impure drug or food, which is the larger offense, which is the more important public interest, this Commission does not step in and try to interfere. But we do handle a large number of cases and the Food and Drug Administration have referred to us innumerable cases where they did not have the jurisdiction because of the distinction which I have explained. And when it is not a question of public health, but a question of filching the public of some of their hard earnings by misrepresenting the therapeutic value or something in relation to the food or drug or cosmetic, it is a commercial proposition and not a health proposition.

I thank you gentlemen very much.

Senator CLARK. Thank you, Judge.

(The excerpts previously referred to are as follows:)

Excerpts from decisions of Federal courts dealing with the powers and jurisdiction of the Federal Trade Commission with respect to false, fraudulent, and misleading adver tising, misbranding, misrepresentation, and so forth.

Section 5 of the Federal Trade Commission Act reads in part as follows:

"That unfair methods of competition in commerce are hereby declared unlawful.

"The commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, and common carriers subject to the acts to regulate commerce, from using unfair methods of competition in commerce.

"Whenever the commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition in commerce, and if it shall appear to the commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect, and containing a notice of a hearing upon a day and at a place therein fixed at least 30 days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission, to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition in question is prohibited by this act, it shall make a report in writing in which it shall state its findings as to the facts, and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition."

1. UNFAIR METHODS OF COMPETITION

"The words 'unfair methods of competition' are not defined by the statute, and their exact meaning is in dispute. It is for the courts, not the Commission, ultimately to determine as matter of law what they include. They are clearly inapplicable to practices never heretofore regarded as opposed to good morals because characterized by deception, bad faith, fraud, or oppression, or as against public policy because of their dangerous tendency unduly to hinder competition or create monopoly", *Federal Trade Commission* v. *Gratz* (40 Sup. Ct. 572).

In the Winsted Hosiery Co. case (42 Sup. Ct. 384) the respondent sold under wear under brands or labels such as "Natural Merino", "Natural Worsted" or "Australian Wool," none of which was all wool. The order of the Commission requiring respondent to cease this practice was set aside by the Circuit Court of Appeals but upheld by the Supreme Court on certiorari. The latter court in its opinion reversing the Circuit Court, stated:

"As a substantial part of the public was still misled by the use of the labels which the Winsted Co. employed, the public had an interest in stopping the practice as wrongful; and since the business of its trade rivals who marked their goods truthfully was necessarily affected by that practice, the commission was justified in its conclusion that the practice constituted an unfair method of competition; and it was authorized to order that the practice be discontinued."

In *Royal Baking Powder Co.* v. *F. T. C.* (281 Fed. 744) the Circuit Court of Appeals for the Second Circuit held that where a manufacturer, by employing false and misleading labeling and advertising, induced the public to believe that a phosphate baking powder which it was manufacturing was the same as a more expensive cream of tartar baking powder which it had formerly manufactured; this misrepresentation was an "unfair method of competition", which can be prevented by the Trade Commission.

The intent of the Congress in creating the Federal Trade Commission is given recognition by the court in this case in the following language:

"The purpose of the Congress in creating the Federal Trade Commission was aimed at just such dishonest practices, and business concerns that resort to dishonest devices of this nature must understand that they cannot add to their revenues or maintain their business standing by methods of competition which the law brands as 'unfair' and therefore unlawful."

The circuit court of appeals in the *Winsted Hosiery case*, supra, had reversed the order of the Commission, which order was later sustained by the United States Supreme Court. In affirming the order of the Commission in the *Royal Banking Powder case* this circuit court explicitly states:

"The reversal of the case by the Supreme Court (*Federal Trade Commission* v. *Winsted Hosiery Co.*, supra) has established the principle that advertisements which are false in fact constitute an unfair method of competition, although

it was one commonly practiced and not intended to mislead the trade. The labeling of commodities in such a way as to deceive the public is an unfair method of competition. The manufacturer must not brand his goods as "wool" when they are part wool and part cotton; and it is now made plain that the statute has invested the commission with jurisdiction to order anyone who misrepresents the quality of his goods in his advertising to cease and desist from such unfair methods of competition." (*Royal Banking Powder Co.* v. *Federal Trade Commission*, 281 Fed. 744).

In the *Guarantee Veterinary Co.* case the testimony showed that the respondent had published advertising matter containing false and misleading statements and the analysis of respondent's product showed it lacked 10 of the 16 ingredients stated in its advertisements. The Court in affirming the Commission's order stated:

"The testimony shows conclusively that the petitioners had been publishing advertising matter containing false and misleading statements and had used an unfair method of commerce, and we think the Commission was quite within its right in issuing the order in the form it did. In such cases the Commission must exercise its discretion in view of all the circumstances." *Guarantee Veterinary Co.* v. *Federal Trade Commission* (285 Fed. 853).

In the Kay case the Commission ordered the respondent to desist from falsely representing that a so-called "radium" product advertised and sold by him contained radium or possessed radioactive properties, the testimony showing that the product did not possess any appreciable radioactivity. The Court held that:

"The evidence before the Commission amply established the fact that the respondent, Kay, had advertised in various magazines, some of them in general circulation, that his product was radium. The cases, *Federal Trade Commission* v. *Winstead Hosiery Co.* (258 U. S. 483, 42 S. Ct. 384, 66 L. Ed. 729); *Royal Baking Powder Co.* v. *Federal Trade Commission* (C. C. A.; 281 F. 744); *Indiana Quartered Oak Co.* v. *Federal Trade Commission* (C. C. A.; 26 F. (2d) 340); and cases cited, hold that false labeling and advertisements which are false in fact constitute an unfair method of competition, placed within the cognizance of the Federal Trade Commission by section 5 of the Trade Commission Act."

The Circuit Court of Appeals for the Seventh Circuit in affirming the order of the Commission requiring the respondent to cease and desist from certain acts states that—

"The following propositions of law fully support the ruling:

"False and misleading representations resulting in deception of the public are matters of public interest which the Commission has power to prevent." *Federal Trade Commission* v. *Winsted Hosiery Co.* (258 U. S. 483); *Federal Trade Commission* v. *Kay* (35 F. (2d) 160).

"The Commission's jurisdiction is not limited to practices which tend to create a monopoly but embrace false and fraudulent advertising, misbranding, and other practices which result in deceiving the public. Such practices injure competitors who do not use them. *Federal Trade Commission* v. *Winsted Hosiery Co.*, supra; *Royal Baking Powder Co.* v. *Federal Trade Commission* (281 Fed. 744); *Federal Trade Commission* v. *Kay*, supra.

"The sale at the same time of a cyclopedia under two different names is an unfair method of competition, which ruling is supported in principle by *Fox Film Corp.* v. *Federal Trade Commission*, supra.

"Practices opposed to good morals because characterized by deception, bad faith, fraud, and oppression are unfair methods of competition. *Federal Trade Commission* v. *Gratz et al.* (253 U. S. 421)." *Consolidated Book Publishers* v. *Federal Trade Commission* (53 Fed. (d) 942).

The same court in denying the petition of respondent to set aside the order of the Commission requiring respondent to cease and desist from (1) using the term "Sani-Onyx, a Vitreous Marble", or the term "Sani-Onyx", as a designation of the product manufactured by it and (2) representing in its advertising matter or by other means, that the product which it manufactures is marble, or onyx, states that

"Labeling and advertisements of the kind described in the findings and shown by the record constitute an unfair method of competition, which the Trade Commission has authority to forbid. (*Federal Trade Commission* v. *Winsted Hosiery Co., supra; Federal Trade Commission* v. *Kay*, (C. C. A. 7) 35 Fed. (2d) 160, 162; *Masland Duraleather Co.* v. *Federal Trade Commission*, (C. C. A. 3) 34 Fed. (2d) 733; *Indiana Quartered Oak Co.* v. *Federal Trade Commission* (C. C. A. 2) 26 Fed. (2d) 340; *Royal Baking Powder Co.* v. *Federal Trade Commission*, (C. C. A. 2) 281 Fed. 744.) *Marietta Manufacturing Co.* v. *Federal Trade Commission*, 50 F (2) 641.

Senator CLARK. We will now hear from Elisha J. Hanson. Is Mr. Hanson here?

(No response.)

Senator CLARK. We will now hear from Mr. Allen.

STATEMENT OF R. M. ALLEN, REPRESENTING THE AMERICAN PURE FOOD LEAGUE

Mr. ALLEN. Mr. Chairman and members of the committee I appear as counsel for the American Pure Food League. It was organized during the campaign in 1906 to secure the present law. It grew out of the Senate Conference Committee so to speak.

With your leave I will file a letter that the League has prepared, with some amendments which have been discussed with Senator Copeland and Mr. Cambell, and we feel that if not in form they will be put in in substance.

Senator CLARK. That may be done.

(The letter is as follows:)

AMERICAN PURE FOOD LEAGUE,
Cranford, N. J., March 7, 1935.

DEAR SENATORS COPELAND AND CLARK: The American Pure Food League is entirely a voluntary organization, those advising contribute the service. As counsel for the League, may I submit recommendations for amendments to the Copeland bill, S. 5, Committee Print No. 3?

With these recommendations included in effective form the League petitions Congress to pass the bill and asks all friends of honesty in the sale of food and drugs to work for its passage.

During the successive efforts to secure the act of 1906, there was an informal committee of the representatives of groups supporting the law. Miss Alice Lakey of Cranford, N. J., represented the General Federation of Women's Clubs and the National Consumers League. She organized out of that committee the American Pure Food League, a voluntary organization, with those advising it contributing their services. Miss Lakey has held and holds, everywhere, the trust of American women because of her unselfish and intelligent pure food work. Throughout the years, from 1905 to date, night and day, she has kept the pure food candle burning in her window.

With an effort to contribute out of good judgment, my appearance for the League is also out of sentiment.

Coming out of college into pure food I had some very honest and able teachers in food and drug control: my chief Dr. M. A. Scovell and Dr. J. N. McCormack of Kentucky, Dr. Harvey Wiley, Dr. E. H. Jenkins and J. B. Noble of Connecticut, A. H. Jones of Illinois, Dr. Woods of Maine, Dr. Albert E. Leach and George M. Whitaker of Massachusetts, Dr. R. E. Doolittle of Michigan, Dr. Julius Hortvet of Minnesota, Dr. E. F. Ladd of North Dakota, Horace Ankeney of Ohio, J. W. Bailey of Oregon, Dr. William Frear, John Hamilton and Jesse H. Cope of Pennsylvania, C. P. Sherwood and Dr. James H. Shepherd of South Dakota, Prof. Elton Fulmer of Washington, J. Q. Emery of Wisconsin, all of whom have passed on.

When Dr. Wiley died I sent a telegram to President Hoover which read,

"The thousands who fought with Dr. Wiley for pure food and the millions of consumers who daily benefit from his life work would all join me in the request that he be buried in Arlington. He qualifies as a Civil War soldier."

May I add that the old Wiley pure food guard passes the mantle and the sword on to W. G. Campbell with their unanimous, united, and fighting support.

None are superior and few equal Mr. Campbell's knowledge and experience in food and drug control law enforcement. Those who oppose this bill or who have lost in the courts against him, particularly remark about his integrity and his fairness. Personally, neither the trade nor the consumer could have anything better done than to have his own draft of the law, and he supports the recommendations which the League here makes.

Senator Copeland was an able health commissioner of New York City. Dr. Lederle, aided by the sanitary work of Dr. Pease in the State laboratory, Nathan Straus, the New York milk committee, with the membership and backing of

Franklin D. Roosevelt, made a big reduction in infant mortality. In his few years as health commissioner, aided by a staff of such able men as Dr. Parks, Dr. Copeland reduced the death rate of children under 1 year from 90 to 65 in every 1,000 births.

Senator Copeland has shown much patience and open-mindedness in giving everybody a hearing. The time has come to write the final good bill and for its friends in and out of the trade to get behind it.

Previous to 1900, Dr. Wiley held several national pure food congresses in which pure food officials, manufacturers, and dealers discussed, in good temper, needs for Federal and State pure food laws. The Association of State Officials held such congresses, particularly in 1903 to 1904, including the International Pure Food Congress and the exhibit of adulterated foods at the St. Louis World's Fair and to which Mark Sullivan gives prominence, particularly as it showed up coal-tar dyes in foods, in his second volume of Our Times.

At these meetings differing views were brought into open opportunity to reach the truth. The man who claimed that milk could not safely be distributed without a chemical preservative was put on the program along with N. B. Gurler, of De Kalb, Ill., who produced certified milk and sent it, without chemical preservatives, across the ocean and won the grand prize at the World's Fair in Paris.

In addition to the experience and conclusions of others, the recommendations presented come out of some 14 years in charge of the food and drug control work in Kentucky; secretary, during the formative period of State laws and the time of the passage of the Federal Foods and Drugs Act of 1906, of the National Association of State Officials; and special assistant to Attorney General Bonaparte in pioneer cases arising under the Federal act.

Kentucky was one of the pioneer States in effective food and drug control and did a large amount of constructive food sanitary work. We handled, during the time I had charge, some 40,000 complaints, including both food and drug adulteration and misbranding. We had, during the years from 1905 to 1910, the record of helping to cut, for example in Louisville, the death rate of children under 3 years of age to one-half of former years. We wrote, and the legislature of 1910 passed, the food and drugs act of 1910 with its clear, simple and strict protection to the consumer and very fair administrative provisions for dealing with the trade. We wrote, and the legislature passed, the model food sanitary act of 1916.

I understand that the amendments which we recommend have been agreed to by Mr. Campbell and I feel that they will be accepted, if not in form, in more effective form by Senator Copeland and the subcommittee.

A recommendation is made for amendments to S. 5, Committee Print 3, as follows:

Page 4, section 301 (a), (2), line 15, insert after the word "substance" the words "which may be injurious to health" so that this part of the section will read:

"(2) If it bears or contains any added poisonous or added deleterious ingredient which may be injurious to health or which is prohibited by section 304."

The reasons for this recommendation are "dangerous" used in (a) (1) of section 301 may be held the standard of Congress for the amounts of harmful ingredient under this provision. "Injurious" appears in the State laws, in the Federal act of 1906 and has been adjudicated to the full protection of the consumer by the Supreme Court.

Page 4, section 301 (a) (4) eliminate the words "have been" in line 22 and substitute the word "be" so that the line will read: "whereby it may be rendered injurious to health".

The reason for this is at once plain to all who have worked to reduce infant mortality and know the methods for doing it. Prevention of the food coming in contact with insanitary conditions is the only safe way.

Further, in exercising sanitary authority in interstate commerce, Congress should do it as experience has shown the only safe and protective way to do.

For dairymen shipping milk in interstate commerce and food manufacturers this kind of inspection, in cooperation with the States and cities will help to find and remove the cause rather than waiting for the Government to coldly seize the product, because the food itself is contaminated.

Page 5, section 301 (a) (6) line 3, and at the end of the section on sanitation add:

"The Committee on Public Health shall certify to the Secretary of Agriculture for adoption under (3), (4), (5), and (6) of (a) of section 301 uniform rules and regulations to carry out these provisions, including regulations to insure, in inspections hereunder, cooperation with State and municipal public health and food

control authorities; *and provided further*, That no person, firm, or corporation shall be prosecuted for violation of these sanitary provisions without first being given notice to abate or correct the insanitary condition and failure, within a reasonable time so to do."

Particularly do I ask Senator Copeland to join me in this recommendation. In Kentucky, with the identical sanitary provisions which I have outlined we reduced the death rate among children, under 3 years of age, in Louisville, Ky. from 960 in 1905 to 437 in 1910. Dr. Copeland did the same in New York.

Page 5, (c), the coal-tar color provision add at the end thereof the following:

"Provided that such coal-tar color or other artificial color shall not be used in any food for the purpose or effect of deception and that such deceptive use shall not be made legal under any labeling or other provisions of this Act."

Such provision will not prohibit any culinary use of harmless color not used so as to deceive the consumer.

Two needs for this addition, in a way which the average man and woman will understand may be given.

Oranges, tomatoes, and raspberries are, now, dependable sources of the needed vitamin C. The child should not be cheated out of health, nor the fruit and vegetable grower out of the right reward for his or her toil, through unfair competition from the aniline dye factory.

"Strawberry", "raspberry", "cherry", "orange", "tomato" belong as much to the producer who toils, the railroad which hauls, the preserving plant which packs and the child which must be fed for growth and good health as do private trade marks to their owners. The same principle of law which protects the private trade mark to its owner applies with equal need to the names which identify the genuine to the consumer and protect the producer in fair trade to his toil.

Would any owner of a private trade mark stand idly by if one appropriated it, boldly on a label, with the explanation that the product was made in "imitation" of or was "colored" like.

No. You would be in court the next day. Are not such genuine food names as "orange" or "tomato" entitled to the same protection? Chief Justice Hargis of the Kentucky Court of Appeals would not allow an infringement of the "Avery" plow trade mark to be sailed "by the trade-mark pirate", "through the Charybdis and Scilla of the law by any deceit known to the inventive brain of man".

Let's give the kid's trade name "Orange" which identifies a needed food thing the same protection from coal-tar colors which are against any means of navigation between Charybdis and Scilla.

Mrs. Sarah Vance Dugan, director of the bureau of foods and drugs of the Kentucky State Board of Health, who succeeded me and is doing a much abler job, replying to a telegraphed request for current ice-cream standards said:

"Ice cream must have 10 percent butter fat; no definite standard for amount of fruit in fruit ice cream. Best manufacturers use 30 percent by volume strawberries, approximately 50 percent by volume peaches. Housewives use 30 to 50 percent by volume strawberries, 40 to 60 percent by volume peaches. Do not believe ice cream should be included with confectionery in section 301 (c) of S. 5."

S. 5, Committee Print 3, does not now take ice cream away from the rest of the law and prohibits alcohol in ice cream, as Senator Copeland intends.

I agree with Mrs. Dugan. I have no objection, if the standard amount of cream and strawberries is used, to touching it up with harmless color. Argument that color is used in butter has been used. If the ice-cream maker conforms to the same rigid standard for butter-fat content, the argument can apply, but not otherwise.

"Strawberry ice cream" should be made out of cream and strawberries. We propose to make 10 gallons of "strawberry ice cream" so we go or should go to the dairy farmer for, say, 7 and not less than 6 gallons of 18 percent butterfat "cream." We go to the strawberry grower or the fruit preserver for 6 quarts of strawberries.

Put a happy-looking dairy farmer, a happy-looking fruit grower, and a pink-cheeked, healthy child in this picture.

Look at another 10-gallon ice cream freezer, instead of cream, a mixture with too little vitamin A bearing butterfat; instead of 6 quarts of strawberries, 1 quart is used. Aniline yellow makes it look like the yellow of genuine cream and aniline red makes it look like it contained genuine strawberries.

Place in this picture a worn and worried dairy farmer and a ragged strawberry picker whose profitable reward is taken away by the unfair trade, and add the child, a rich or a poor child with sallow cheeks and thin body. Label the thing

on the can "imitation" or "color added"? Label a keg a brass-plated tin dollars "imitation gold" as protection compliance with the counterfeiting law?

The artificial strawberry ice cream sells for nearly as much as the genuine. The dairy farmer and fruit grower are cheated out of fair trade and the child out of needed vitamin A. Part of the cream and strawberry money rightfully belonging to the farmer goes to the aniline dye factory and the other part as gain to the strawberry ice cream counterfeiter.

Give the forgotten dairy farmer and fruit grower their rightful reward for their toil, through fair trade, and forget all need for governmental relief. Give the child the genuine, growth-promoting, health-protecting food.

Here, then, are unanswerable and compelling reasons for prohibiting the fraudulent use of coal-tar colors, in this "new deal" in food.

Page 9, line 10 strike out (k) which reads:

"If it bears or contains any artificial color, artificial flavor, or chemical preservative and it fails to bear a label stating that fact."

and substitute:

"(k) If it bears or contains any artificial color not used for the purpose or effect of deception, or chemical preservative not prohibited under (a), (2) and fails to bear a label stating that fact. Provided that the Secretary of Agriculture shall establish uniform regulations for exempting labeling in any case where the use of color does not violate any of the provisions of this Act relating to foods."

In administrative authority the American Pure Food League urges the need for centralized authority and responsibility. I am one who helped to put the hearing clause in the act of 1906 and the guaranty of purity clause which protect the innocent from prosecution for that which the innocent did not do.

Two review boards are proposed now, one a separate board, in the McCarran bill and a Federal Trade Commission review of advertising in Congressman Mead's bill. No review should exempt anyone from any of the penalties provided in Senate 5, Committee Print 3.

Forty-five States passed, in the early twenties, the printer's ink bill. It reads, using New York's statute:

"ADVERTISING LAW (NEW YORK STATE) CHAPTER 41, ARTICLE 40

"SEC. 421. Any person, firm, corporation, or association, or agent or employee thereof, who with intent to sell or in any wise dispose of merchandise, real estate, service, or anything offered by such person, firm, corporation, or association, or agent or employee thereof, directly or indirectly, to the public for sale or for distribution, or with intent to increase the consumption thereof, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or an interest therein, makes, publishes, disseminates, circulates, or places before the public in this State, in a newspaper, magazine, or other publication, or in the form of a book, notice, circular, pamphlet, letter, handbill, poster, bill, sign, placard, card, label or tag, or in any other way, an advertisement, announcement, or statement of any sort regarding merchandise, service, or anything so offered to the public which contains any assertion, representation or statement of fact that is untrue, deceptive or misleading." (Added by L. 1915, ch. 569; as amended 1921, ch. 520, Sept. 1.)

This is the briefest and most complete application of the seventh commandment to business since Moses brought "thou shalt not steal" down from Mount Sinai.

It may be that the Federal Trade Commission could be given or already has authority in its broad power for "the public interest" to consider complaints from a State where the violation of the public interest comes in from interstate commerce. This uniform State statute is a very effective law.

To do the job the Federal Trade Commission would have to duplicate the scientific machinery of the Food and Drug Administration. I have reviewed for the league the decisions of the Federal Trade Commission as food and drug advertising and labeling have related to unfair trade. The Commission has made some good decisions.

If responsibility for the enforcement of this law is to be placed on the Secretary of Agriculture and all authority taken away, then either legislate a separate board or turn it over with all machinery to the responsible authority. Personally I rather favor a modified form of Mr. Dunn's board of review in Senate 580. I do not think it necessary. The committee on public health and the committee on foods will take care of all sought and needed.

But these administrative matters can and will be ironed out by the Senate committee and, I feel, in full fairness to the trade and with full protection to the consumer.

Let me make this suggestion to the food and drug manufacturers. Some of your counsel may not be looking to all that you need. I, too, am a member of the bar, but with rather long experience in food inspection and management. May I suggest that extensive and complicated machinery will repel administrative cooperation in helping a well-intentioned manufacturer out of difficulty where there is complete absence of intent to commit fraud. Out of experience as an official, if each case had to be prepared and dealt with, for determination by another authority, I would not, could not, take a violation up and do helpful justice where it appears deserved. All the time I would have to be a cold prosecutor.

Let me urge on my brethren in the food and drug trades not to go to the length of getting a complicated administrative machinery in which justice and common sense cannot operate. The food and drug manufacturers are on all fours with the consumer in not wanting this piling up of expensive and tangled administrative machinery.

The secretary of the American Pure Food League has asked if Senate bill 5, Committee Print 3, conforms to the constitutional formula laid down by Mr. Chief Justice Hughes in the *Oil cases*. The sections I have covered, in my opinion, do, as do the sections relating to cosmetic and drug adulteration and misbranding. I have not sufficiently studied the administrative sections to give opinion. On the whole, I think the act, Senate 5, Committee Print 3, is well founded in the decision in the *Oil cases* and in the decision by Mr. Chief Justice Taft, in the *Grain Futures Case* (S. U. 1, 67 L. ed. 839) strongly supports the broad power of Congress to act for the "national public interest".

In that decision the Chief Justice said:

"Whatever amounts to more or less constant practice and threatens to obstruct or unduly to burden the freedom of interstate commerce is within the regulatory power of Congress under the commerce clause, and it is primarily for Congress to consider and decide the fact of the danger and meet it. This court will certainly not substitute its judgment for that of Congress in such a matter unless the relation of the subject to interstate commerce and its effect upon it are clearly nonexistent.

"In the act we are considering, Congress has expressly declared that transactions and prices of grain in dealing in futures are susceptible to speculation, manipulation, and control which are detrimental to the producer and consumer and persons handling grain in interstate commerce, and render regulation imperative for the protection of such commerce and the national public interest therein."

Originating as the original Senate 1944 did from the present administration, with the backing of the President for a bill which will be fully protective in every need to the consumer and with fair administrative provisions to the trade, with the backing of the women's clubs who, in turn, are followed by the millions of women and men throughout the country, the committee in Congress have the opportunity to place on the Federal Statutes a real "new deal" in the interstate regulation of foods, drugs, and cosmetics.

With these amendments the league supports the Copeland bill, Senate 5, committee print 3.

Very truly yours,

R. M. ALLEN, *Counsel American Pure Food League.*

Approved.

ALICE LAKEY, *Secretary.*

Mr. ALLEN. There is particularly one suggestion, Senators, which we have made, that I would like to emphasize in a way that is not emphasized in this letter. Section 301 (a) (1) prohibits the sale of a food if it contains an ingredient that is dangerous to health. All right. Now, no. 2 says if it bears or contains any added poisonous or added deleterious substance. And under the oil cases, not which Congress prohibits, but which the committee would prohibit, we feel that by putting in there the words after "injurious", "which may be injurious to health" then it has Congress to legislate as to the thing which is really prohibited. And for that reason, aside from the fact that the word "injurious" is used in the present law, and

all of the State laws, and has been so splendidly adjudicated to the consumer interests by the Supreme Court, I would suggest your thinking of whether, and the Food and Drug Administration thinking of whether, you have not left that section hanging up with the objection raised in the oil cases. And I think that is fully covered, and I say that as a member of the bar with long experience in this work, by putting that word in, Senator Copeland has covered that.

Senator COPELAND. Yes. I think that is a very wise suggestion.

Mr. ALLEN. Senator Copeland, you understand this, and Dr. Arthur McCormick, whom I see here, will understand this, better than anybody else, from the good work that you did as health commissioner in New York City. You took a rather high death rate among children in that city and you very materially reduced it. Now the means by which you did that were preventative, and cooperative wherever possible with the trade.

And to carry that out also to provide a protection of fairness to the little fellow that may ship milk across the State line I would suggest, without suggesting the form, that with a product that may be held up at the border as being unclean that a regulation be put in that the dairyman or the big food manufacturer in the case of unsanitary conditions be given a hearing, not prosecuted on the first charge or finding. I would just suggest that, Senator, and then the taking out in line 22, which I think has already been done, of the words "have been" and substituting the word "be."

On colors, Senator, I think that all food control officials, if they could get the fraudulent use of color out, have no concern about the culinary use, the touching up to make things look attractive.

Senator COPELAND. You are referring now to section (k) on page 9?

Mr. ALLEN. Yes. It is this: You take a 10-gallon freezer and you are going to make ice cream with it. Now, if you will go over there and get 6 gallons of the farmer's cream and 6 gallons of his strawberries, and so much of the sugarman's sugar, and so much of the gelatin man's gelatin, and come here and make a genuine strawberry ice cream I have no objection to your touching it up. I do have objection to your selling that as cream when you have no cream, or little or no cream, and sell it as strawberries when you have little or no strawberries. It is unfair treatment to the farmer and it is unfair to the child when you have touched that up. If you come here and use little or no cream and take yellow aniline and make it look like it, use little or no strawberries, that is a fraud. Can you not distinguish between those two in the bill? I think you can. That is the suggestion we make in here.

Otherwise, with that, Senator, I feel that I can speak in a general way for the very able disinterested men and women, who appear on the letterhead of this league, and put them behind this bill.

May I in closing just make this suggestion: I heard Judge Davis; can you not work it out? The bill is ready to go over. Can you not work it out where his jurisdiction is his and Mr. Campbell's is his? But may I make this suggestion: Do not divide the authority. If you are going to place the responsibility on the Secretary of Agriculture, give the Secretary of Agriculture the authority to assume that responsibility. If you are going to turn it over to the Federal Trade Commission turn it over to the Federal Trade Commission. Do not divide the authority.

I would like to say to my brethren in the food and drug trade that representatives have been down here with a lot of complicated regulations that are going to make it so that an ordinary business man cannot come down to Washington and get a thing done in a simple way or get, you might say, the heart of justice without having to spend an interminable delay with too many committees and too many commissions. The Department of Agriculture can and will do its duty. It has, and has done it efficiently, effectively, and honestly. Now give the part in this bill to that Department, and then give Judge Davis the fair trade part of it. You can let him have concurrent jurisdiction in all fair-trade matters. I do not see why that cannot be worked out. And that is the one thing which seems to be now the stumbling block for the touch-down. Senator, since 1879 you finally have rounded up, I think, an excellent model. Now, you gentlemen get those fine details worked out and let us get together and get it passed as a model pure food law.

The administrative Board of Review is urged by all in the food and drug trades, by the advertising industry and the newspapers and magazines.

I helped to contribute the hearing clause and the guaranty of purity clause in the act of 1906. In no case have these hampered the law. They have aided the administrators to do justice to the innocent.

Now a firm which has invested millions in its trade mark and good will wants, particularly, questions of advertising considered by a Board of Review, to be appointed by the President. How that Board of Review is constituted is of less concern than that both the Food and Drug Administration and the defendant shall have the right of appeal to the courts, if the decision is against the Food and Drug Administration or if it is against the defendant. If the purpose of the Board of Review is, and it is so constituted, to keep the consumers' side, through the Food and Drug Administration, away from the courts, I am against it. But if it is an administrative board, to guarantee against administrative errors affecting the good will built up through many years and, possibly, under which unintentional violations can be constructively corrected and still with an open door from the Board of Review from either side of the courts, I am for it.

Whether this Board of Review is constituted as is contained in Senate bill 580 or whether the review of advertising is passed over to the Federal Trade Commission, give the Department of Agriculture the court review provided in Senate 580. If any part of advertising review is turned over to the Federal Trade Commission, give the Food and Drug Administration freedom to prosecute their charges and the right of appeal from the Commission to the courts in the courts.

It is against the public interest to divide authority. It is very much in the public interest to bring all Government agencies which can stop the false advertising of foods and drugs into cooperation. There is no occasion here for the friends of pure food to do anything to weaken public confidence in the Federal Trade Commission. Honest trade, fair trade, and the control of monopoly are the very basic parts of the "new deal". We depend on the Federal Trade Commission for much of this and its record since 1915 shows it entitled to the fullest of public confidence.

Senator CLARK. Mr. James F. Hoge.

STATEMENT OF JAMES F. HOGE, OF ROGERS, RAMSAY & HOGE, REPRESENTING THE PROPRIETARY ASSOCIATION, OF NEW YORK, N. Y.

Mr. HOGE. Mr. Chairman and members of the committee, my name is James F. Hoge, of New York. I represent the Proprietary Association, the membership of which consists of several hundred manufacturers of medicinal and toilet preparations. They are manufacturers of approximately 80 percent, in volume, of the proprietary products sold in the United States. Most of them are advertisers. Some are among the largest. Their products include many of the best-known trade marks and names in the country.

I also represent numerous individual companies which manufacture medicinal and toilet preparations, and for which my law firm has been general counsel for numerous years.

Those for whom I appear recognize that improved food and drug legislation is required in the interest of the public and in the interest of legitimate industry, holding that the interests of each are interrelated. They further take the position that manufacturers and distributors of drugs and medicinal preparations, indicated as they are for vital human needs, and affecting the public health, must assume the burden of using extraordinary care in maintaining higher standards of quality and in determining the truth of claims made for their products; that claims should be stated in clear terms that are not likely to mislead; that manufacturers and distributors, and not the public must assume the risk of their ignorance or mistake. Their views in these respects have been publicly stated and their position on specific provisions for improved food and drug legislation has taken the form of endorsement of a bill introduced in the House of Representatives by Mr. Mead, of New York, identified as H. R. 3972. I refer to that bill as a definite proposal for legislation and as a declaration of the affirmative position which these manufacturers hold on this subject.

The fact that they are for the Mead bill does not imply that they are opposed to S. 5. They have objections to S. 5, but their objections are to form and specific provision, rather than to improved legislation and to the purposes of S. 5 in that respect.

The form of the legislation is not the most essential feature. It is, however, important. Our position on that is more a preference than an objection. S. 5, although spoken of as a revision of the existing Food and Drugs Act is not that, as to form, because it repeals entirely the existing law.

The Mead bill, on the other hand, is drawn to overcome defects in the existing law. It does not represent piece-meal amendments, but revision. While changing the sequence of the existing law, it retains what is effective and replaces what is defective.

And this form for legislation has the advantages of maintaining provisions that are familiar to all the interests affected by it, preserving court decisions that have been rendered since 1906, and maintaining uniformity that now exists between Federal and State legislation. Many States have food and drug laws modeled on the existing Federal law. In many States the Federal regulations are adopted insofar as applicable. In addition to decisions by Federal

courts construing the Federal act, there have been decisions by State courts construing their respective acts. Revision, therefore, preserves, as to the portion of the existing law preserved, the court decisions and the existing uniformity, and also affords a more likely opportunity for State laws being revised in the same respects as the Federal law is revised.

Our objections to S. 5 are principally to administrative provisions. We have objection to some of the definitive provisions, although most of our objections in those respects fall under the subject of regulations in that our objection goes not necessarily to the prohibited act but to the provision that the Secretary may enlarge upon it by regulations.

It is recognized, of course, that there are circumstances in which the Secretary should have authority to make regulations. That is recognized in the existing law. He must make administrative regulations on procedure, exemptions, tolerances, and, in a few instances, minimum standards. But, by and large, it is possible to state the offenses and the obligations in the law rather than provide that the Secretary may state them in regulations.

I shall discuss only those regulations which affect the manufacturers for whom I appear.

Page 16, section 402 (d) states that a drug shall be misbranded if it does not declare on the label——

Senator COPELAND (interposing). What page is that?

Mr. HOGE. Page 16, Senator, and down about line 12.

Senator COPELAND. That is correct.

Mr. HOGE. That section provides that a label must bear the names of certain named narcotic or hypnotic substances, and a statement "Warning—May be habit forming." I offer no objection to the drugs named. My objection is to the language in lines 13 to 16, for narcotic or hypnotic substances being designated as habit forming by regulations. Our suggestion is that the language in lines 13 and 16, which I just read, be delected.

On page 17, section 402 (f) (2), line 7, provides that a drug shall be misbranded if it does not state on the label:

such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 703, against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application.

It seems to us that that provision is unnecessary in view of the provision in the act that a drug shall be adulterated or misbranded, as we suggest, if it is dangerous to health under the conditions of use on the label, also the provision that the label shall bear complete and adequate directions for use. Our objection to the provision, however, is against the power to prescribe by regulation. And we would suggest that if the committee desires to retain some such provision at that point that it read in this fashion:

such warnings in such manner and form as may be adequate against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health"—

I suggest putting that in that language, Senator—

or against unsafe dosage or methods or duration of administration or application.

I am advised—I am not a doctor—that the language "contraindicated" there, Senator, should go in lest we run into this argument on allergy again.

On page 24, section 601 (b) and in lines 12 to 14, that subsection contains the list of certain diseases for which no drug shall be advertised as having any therapeutic effect. We have no objection to the provision insofar as it names the diseases. Our objection is to the language in lines 12 to 14:

as well as any other disease perilous to the life of the individual or to the public health which may be added to this list by regulations as provided by sections 701 and 703.

And our recommendation is that that language in lines 12 to 14 be deleted.

Certain committees are set up to approve the Secretary's proposed regulations. The committee which is to deal with drugs expressly must not include any person who has a financial interest in the manufacture, advertising, or sale of any drug. If the committee is to be retained, we respectfully suggest that the committee on public health include at least 1, and possibly 2, members who do have a financial interest in the manufacture, advertising, or sale of drugs.

Senator COPELAND. Much the same way as we provide under the food?

Mr. HOGE. Under the food law; yes, sir.

Senator COPELAND. The idea of that, I suppose, is that there may be someone there who knows the manufacturing side and can present its cause, if it has one?

Mr. HOGE. Yes, sir. And your provisions or regulations include many matters highly technical and practical from a manufacturing standpoint. I will mention one; for instance, the tests and methods of assay pertaining to the Pharmacopoeia. I am not discussing that subject myself, but I understand that would be highly technical when you get into tests and matters pertaining to standards set up in the pharmacopoeia, and likewise regulation as to how drugs liable to deterioration should be packaged and labeled. That certainly would involve the manufacturing or the commercial side of it.

Senator COPELAND. Did you suggest some language to cover what you had in mind?

Mr. HOGE. I did not have a suggestion worked out, Senator.

Senator COPELAND. But your idea is to add two members to that committee, as we did in connection with the foods?

Mr. HOGE. For the foods; yes. And perhaps the language pertaining to the food section would be satisfactory. I think that appears on page 30.

I think, Senator, there, on page 27, down in lines 22 to 24, where you are dealing with the food standards, that you have it:

which shall consist of seven members, three of whom shall be selected from the public, two from the food producing, processing, manufacturing, and distributing industry, and two from the Administration.

There is no requirement that the committees meet in session and conduct hearings. It is merely provided on page 30, line 13, that each committee shall convene at the call of its chairman at such time and place as he may designate. And then it goes on to provide that the Secretary shall send to the committees transcripts of the hearings

held by him. I believe in one of the editions of the bill last year it was provided that the committees should meet at least once a year. But if the committees are to be retained, we suggest that the members of the committees be required to sit with the Secretary at the hearings.

Senator COPELAND. You will notice, on line 21.

> Members of the committee shall be given due notice of and may sit with the Secretary.

Mr. HOGE. And may sit. I think last year you had a provision that they should sit at least once a year. I do not remember the exact language, but I think 2,800 did have that. And even if these members of the committees take the trouble to read these transcripts that are sent by the Secretary, some of them long and some short, I doubt if they have quite the personal touch with the facts in the matter they would have if they were present.

Senator COPELAND. Do you mean an attractive, handsome young man like yourself might make an impression on the committee?

Mr. HOGE. Thank you, Senator. I hope there is an implication in that.

Other than those objections mentioned under the subject of regulations, we have objections to the following definitive provisions. Our objections to those I have mentioned under regulations go primarily to the fact they are enlarged under regulation, not to the prohibition of the act itself.

On page 13, section 401 (a) (1) provides that a drug shall be deemed to be adulterated—

> if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.

Our objection to this provision is that it is included in the section dealing with adulteration. Adulteration is not effected by the labeling or advertising, and we suggest that the provision be stricken in section 401 and transferred to section 402, dealing with misbranded drugs.

The importance of this is in connection with seizures, and there is a suggestion which we shall make presently that there should be some limitation upon the number of seizures that can be made without court order as to misbranding. That is the importance of the transfer of this section. And obviously it is only a matter of labeling or branding; for if the labeling or advertising is corrected, the offense is overcome without any treatment on the composition of the drug itself.

The same provision appears on pages 20 and 21 in section 501 (a) dealing with cosmetics.

Senator COPELAND. That is, you would transfer in the same way here you have recommended in the other place?

Mr. HOGE. Yes, sir; I would make the same suggestion there. I think perhaps, there, Senator, on page 20, with respect to adulterated cosmetics, that you would have to do it a little differently than I suggested as to drugs. Perhaps you would not want to transfer the whole section. Perhaps you would want section 501 (a) to read in this fashion:

> If it bears or contains any poisonous or deleterious substance which may render it injurious to health under such conditions of use as are customary or usual.

And that would have the effect, then, of transferring to misbranding if it is dangerous to health under the conditions of use in the labeling or the advertising.

On page 15, section 402 (a), it is provided that any representation concerning any effect of a drug is false under this paragraph if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion. I am advised that it would be quite impossible often to sustain representations in every particular by opinion, because opinion is not absolute and constant. And, likewise, while the distinction in the dictionary is not great between the words "sustain" and "support", we believe that in law there is a distinction and that it is possible to support a representation by opinion when it would not be possible to sustain by opinion. On that the dictionary does not give a great difference in meaning between the two.

I took the trouble to write to Merriam Co., the publishers of Webster's Dictionary, and they made this reply, in part. I quoted the phrase, and they said:

> This sense, which "sustain" already had in early English, of upholding the validity, truth, rightfulness, et cetera, of a claim, objection, possession judgment, or the like, applies primarily to the action of a court and by extension to the action of any authority, the agent of the action being an accepted authority whose decision is incontrovertable.

Furthermore, on that subsection the opinion, by virtue of the definition of "medical opinion" which appears in section 201 (k), on page 3, seemingly excludes the opinion of pharmacologists, physiologists, bacteriologists, and pharmaceutical chemists.

Senator COPELAND. Just a minute, Mr. Hoge. Let us go back to page 15.

Mr. HOGE. Yes.

Senator COPELAND. Do I understand that lines 13 and 14 shall read, according to your view:

> is not sustained by demonstrable scientific facts or supported by a substantial and reliable medical opinion?

Does that cover the thought you have in mind?

Mr. HOGE. Yes; I think that does. I think an opinion you support. I do not believe you can sustain an opinion. The court will sustain one's argument which he supports by his opinion and his authority.

Senator COPELAND. All right. Now, page 3.

Mr. HOGE. Page 3, the definition of "medical opinion", that is line 17, and the particular pertinent part is down at lines 21 and 23. I think that definition excludes the opinion of pharmacologists, physiologists, bacteriologists, and pharmaceutical chemists whose opinion oftentimes is more important than the physician's on the effect of a drug.

Senator COPELAND. You would like to have added, then, after "medical" in line 21, "and pharmacological."

Mr. HOGE. Yes. Now, let us see if that would work out. You could not work it that way, I do not believe, because you further modify it by the words "the practice of which is licensed by law in the jurisdiction where such opinion is placed in issue", and pharmacologists are not licensed. In S. 2800 you had "and the term 'medical' opinion means the opinion of physicians, pharmacologists, dentists, or veterinarians."

Senator COPELAND. We got in trouble there because it did not say "chiropodists, chiropractors", et al. You can readily believe that in writing a definition it is not easy to get in everybody.

Mr. HOGE. I know that is so, Senator. I have a suggestion that would probably overcome the difficulty. You can amend your definition of "medical opinion." I would suggest, however, that you go back to page 15 where you had the subsection under discussion and let lines 11 to 15 read this way:

> Any representation concerning any effect of a drug shall be deemed to be false if such representation is not supported by demonstrable scientific facts or substantial medical or scientific opinion.

That would include the pharmacologist and would not make necessary disturbing the definition in section 201.

Now, the same provision appears on page 24 in the section on advertising. That is lines 2 to 5, and I make the same suggestion there.

Now, from the standpoint of public health we would like to suggest a further subsection in the misbranding sections on foods, drugs, and cosmetics, but particularly as to drugs.

Senator COPELAND. On what page?

Mr. HOGE. Well, that would take us back into section 402 and it could go anywhere among one of those subsections, perhaps inserted on page 20 between lines 5 and 6 as a new subsection, and it would read that a drug is misbranded—

> if it bear a copy, counterfeit or colorable imitation of the trade mark, label, or identifying name or device of another person.

In our practice with infringements of trade marks, counterfeiting, and other forms of passing off, we have found that many potent drug are sold under copies, counterfeits, or colorable imitations of the trade marks or identifying names of reputable and well-known products. Of course, so far as that is the problem of the individual manufacturer, he would have to go on fighting it, of course, and he will, but it has seemed advisable to us to have such a provision included in a law of this kind.

Senator CLARK. Mr. Hoge, that suggestion is simply for the protection of the individual manufacturer rather than the public, is not it?

Mr. HOGE. I do not think so, Senator, because you will find the most potent drugs Luminal, Theominal, and Pyramidon, all exploited under counterfeits. Notwithstanding that, the manufacturer would have to go on. Of course, the Administrator would not have to use it when he does not want to use it.

Senator COPELAND. Do you have protection under the patent and copyright law now?

Mr. HOGE. You do not have under the patent law unless you have a patent. Not many of them have a patent. Your principal protection is either under the trade-mark law, when you have a trade mark, and, of course, some of the drugs do not have trade marks, some of the potent ones, or you have protection under the common law of unfair competition, and for counterfeiting many States have criminal laws.

Senator COPELAND. Let me ask you this question, Mr. Hoge. Would you not have protection from the Federal Trade Commission now, would not that cover such a suggestion?

Mr. HOGE. Yes; there is protection there, too, and the Federal Trade Commission has handled some such cases.

Senator COPELAND. But your judgment is it ought to be written in here?

Mr. HOGE. I think so; yes, sir. I think it ought to be in a law of this sort. The Administrator can suit himself as to when he uses it and when he does not use it, but it is there when he wants it.

Now, a further suggestion, and that is, in view of the far-reaching provisions on misbranding and advertising, and the criminal aspect of some of it, we suggest the inclusion of a subsection which provides as follows:

> When construing and enforcing the provisions of this act reasonable allowances, consistent with the purposes of the act shall be made for (1) abnormal individual reactions to food, drugs, and cosmetics, and (2) harmless claims recognized by and under the common law.

That is a suggestion on the matter of allergy which has been mentioned from time to time in these hearings.

Senator COPELAND. Where would you put it in the bill?

Mr. HOGE. I think, perhaps, Senator, that that should be written into each misbranding section with respect to foods, drugs, and cosmetics.

Senator COPELAND. I suppose also that might be included in the report on the bill.

Mr. HOGE. Of course, that would go to the intent of Congress.

This matter of harmless trade claims I have always thought was in the law, whether it was written here or not. It is a matter of the common law, but when you make such comprehensive statutory definitions as we are making, that labeling and advertising shall be considered false. If it is false or misleading in any particular, under any of the provisions of the act, there might be a question. I do not think, perhaps, that that is as great a matter as some reference to the matter of abnormal individual reactions.

Now, section 711(a), page 41, is the beginning of the section on seizures, and it provides that any article that is adulterated or misbranded may be seized while in interstate commerce or at any time thereafter by libel. And then on page 43 it provides:

> but if a chief of station or other employee of the Administration, duly designated by the Secretary, has probable cause to believe that such article is so adulterated as to be imminently dangerous to health, then, and in such case only, the article shall be liable to seizure by such chief of station or employee.

Such chief of station or employee may seize the article without any legal process whatever. All he must do is report what he has done after he has done it to the United States attorney, who will then prepare a libel.

Now, the chief importance of that section on page 43 is in connection with the provision I referred to a moment ago, that drugs and cosmetics are deemed to be adulterated if dangerous to health under the conditions of use in the labeling or advertising. That, for administrative purposes, of course, means if the Administrator thinks it is dangerous. It so provides, if he has probable cause to believe that it is dangerous.

Now, the employee designated by the secretary, or a station chief, hearing advertising over the radio, or reading it in the paper, might come to the conclusion that a drug or cosmetic is adulterated, and if

he thinks it is adulterated so as to be imminently dangerous to health, he goes out and seizes it without any process at all.

Now, I have a suggestion with respect to section 711 (a), and I will treat it while I am on it. That is page 42. There was a suggestion here the other day that in line 9 there be added the words, "if a court considers it necessary," "considers seizure necessary". I do not think that accomplishes anything, because it does not provide there shall be any notice, and indeed you cannot very well provide there shall be notice in an in rem proceeding, and the judge seeing one libel coming to his desk in New York is not told or informed that a libel is at the same time going to the desk of a judge in Detroit or Trenton or some other place.

I would suggest in line 9 there be added this language:

Provided, however, That not more than one seizure action shall be instituted in cases of alleged misbranding except upon order to show cause, and then upon a showing by the Secretary that such article is misbranded in manner or degree as to render such article imminently dangerous to health, or that such alleged misbranding has been the basis of a prior judgment in favor of the United States in a criminal prosecution or libel for condemnation proceeding against such article under this act: *And provided further,* That said single seizure action shall, on motion, be removed for trial to a jurisdiction of reasonable proximity to the residence of the claimant of such article.

Senator COPELAND. Did not we have some such language in one of the bills last year?

Mr. HOGE. Yes, in S. 2800 at one time you had a provision that there should not be more than one seizure made for misbranding, except in cases involving imminent dangers to health and in cases where a prior judgment had been rendered in favor of the United States, and the condition that the labeling of all the products was the same. I think that was it.

Now, that which I suggested just now has a relation also to the italicized matter on page 45. That is one of the principal faults with multiple seizures, that seizures can be made any place in the United States, and it makes no particular difference how many. If 4 or 5 or 6 are made, the manufacturer must then transport his witnesses and his data perhaps from New York to San Francisco, if that is where the seizure action is pending, or to New Orleans or some other place. I do not ask that the trial be brought right into the home of the manufacturer. I realize that the administrator sometimes has reasons why he does not want to do that. I do think if goods are seized on the Pacific coast, for instance, and the manufacturer lives in New York, that the trial might be moved to Trenton or to Albany, or even Philadelphia. You can get there in 2 hours.

Senator COPELAND. Have not we answered that on lines 10 and 11 on page 45, "on application of the claimant, seasonably made, may be tried in such jurisdiction"?

Mr. HOGE. I will come to that in a moment. As you have it now it would mean simply this, that if the seizures are made on the Pacific coast and you live in New York, or the manufacturer lives in New York, it would be a matter of determining which point on the Pacific coast was nearest to New York. Now, a suggestion was made the other day by one of the witnesses that you add to line 14:

In cases of multiple seizure at least one such seizure shall be made in the jurisdiction of the United States District Court where the manufacturer resides, or if impossible to locate it there, then in a near jurisdiction.

In the first place, Senator, you cannot make a seizure in the jurisdiction in which the man resides, except in very extraordinary circumstances, because there is no interstate commerce. Perhaps if the administrator could find a shipment of the goods at the depot already consigned out of the State, with the bill of lading on, perhaps under the decisions that would be interstate commerce and he could seize it, but other than that he could not seize it in the man's own jurisdiction. So that suggestion does not accomplish anything. In the first place, I do not think the administrator should be restricted. He might not be able to find it in a jurisdiction near the manufacturer's residence.

Senator COPELAND. Are you suggesting substitute language?

Mr. HOGE. Yes. I will read the whole matter so as to get it straight. I would suggest on page 45, lines 2 to 14, that we have this:

In cases of articles of food, drugs, or cosmetics seized under the provisions of this section when the same issues of adulteration or misbranding under the provisions of this act, raised by the same claimant, and pending in various jurisdictions, the cases, on application of the claimant, seasonably made, may be removed for trial to a jurisdiction of reasonable proximity to the residence of the claimant. Separate verdicts shall be rendered in each case and judgments entered upon such verdicts in conformity with the provisions of this section.

Senator CLARK. Mr. Hoge, let me suggest to you, and to any of the witnesses who have amendments they desire to propose, that they reduce them to writing and file them with the stenographer, so that they may be made a part of the record. In connection with that, let me explain to all who may desire to appear before the committee, that this subcommittee is constituted for the purpose of holding hearings and not making recommendations on the bill to the full committee. In other words, it would be our purpose to report back the hearings to the full committee for such consideration as they may see fit to give them. Therefore, any witness who has a prepared statement I would suggest that he file it with the clerk rather than read it in extenso, because it would serve the same purpose in being reported to the full committee. I do not mean that applies to you, Mr. Hoge, but in view of the fact that you are offering amendments, I deem it proper to make that suggestion.

Mr. HOGE. That is all right.

On page 32 is "Factory inspection."

Senator COPELAND. Mr. Hoge, you are going to leave with us, are you not, that memorandum that you have?

Mr. HOGE. On factory inspection?

Senator COPELAND. On this other matter.

Mr. HOGE. Yes; I would be glad to, Senator.

Now, on "Factory inspection", our objection there is largely to the penalty in subsection (b) on page 33, line 14, down to the bottom. It is provided there that if inspection is refused or permission denied by the manufacturer that the district courts are authorized to enjoin the shipment of goods, whether they are adulterated or not. Our objection is not to inspection but to the penalty. The goods may not be adulterated at all and the circumstances on which the permission to inspect was denied may have been very pertinent. I will file, Mr. Chairman, our suggestion as to how subsection (b) on page 33 should read. In a word, it is just to compel the inspection.

There has been something said about the whole section, if I might have just a minute on that, as to its constitutionality. I do not mean to launch into a long constitutional argument, but I would question subsection (a) of that section ordering inspection in order adequately to protect public health and welfare. While, of course, that is a perfectly proper purpose, my own thought is that factory inspection in this bill has got to rest for its constitutionality on the commerce clause, just as in the meat inspection act, that rests on the commerce clause to prevent the shipment in interstate commerce of meats that are not fit for consumption, and so it seems that this section should rest on the commerce clause so as to prevent the shipment in interstate commerce of goods that are adulterated or misbranded.

Now, for that purpose it seems that subsection (a) should provide that if it cannot be determined, after a food, drug, or cosmetic has entered interstate commerce, whether it is adulterated or misbranded, that inspection may then be had.

Senator COPELAND. I think that has been recognized by the committee, that particular weakness.

Mr. HOGE. I will close in just a minute, Mr. Chairman. Finally, our position on advertising is it should be administered by the Federal Trade Commission. It is not a matter of transferring the control of advertising to the Federal Trade Commission, it is a question of transferring the control from the Federal Trade Commission. Advertising is there now. The Mead bill, which we have endorsed, proposes that the jurisdiction and powers of the Federal Trade Commission be enlarged to cover advertising which is false or misleading, for all the purposes of this legislation, and to make unnecessary any showing by the Commission that such advertising is an unfair method of competition. Thus the Raladam case, mentioned here and elsewhere, to the prejudice of this suggestion, and the limitation upon the Federal Trade Commission's jurisdiction would be of no further consequence.

Advertising presents a serious problem. If we were concerned only with advertisements which were false in the ordinary meaning of that word, or if we were concerned only with offenders who were deliberate and malicious, there would be no problem. But, for every advertisement which is deliberately and maliciously false, we will be concerned with hundreds of advertisements that are not deliberately false and with advertisers who do not deliberately falsify.

We have no objection to criminal prosecution of false advertisements when the public health is involved. But, under this proposed legislation, there will be many advertisements alleged to be false or misleading within the definitions and purposes of this legislation which do not immediately affect the public health.

We question the soundness of legislation that makes such offenses criminal and affords the opportunity for corporations and persons who are not criminally inclined being prosecuted in criminal courts with the stigma and embarrassment necessarily incurring from such prosecution.

That is the basis for our position on the matter of the Federal Trade Commission handling advertisements. That procedure is of a civil nature—an order to cease and desist, with the punishment for violation of the cease and desist order as in contempt of court. That is a serious punishment. We have no objection to injunction against false

and misleading advertisements. And, as above stated, we have no objection to criminal prosecution in the case of advertisements which involve the public health. We suggest that in the section of S. 5 dealing with misbranded food there be added a section similar to section 401 (a) (1) which we have already suggested be transferred from the section on adulteration to the sections on misbranding as to drugs and cosmetics providing that the article be misbranded.

"if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof." And that, in lieu of the criminal prohibitions as provided in sections 708 (a) (4) and (5), (pp. 34 and 35), there be inserted the provisions of section 5 of the Mead bill, providing that false advertisements generally be referred by the Secretary to the Federal Trade Commission; that the Secretary be granted the authority, just as the Mead bill grants such authority under section 14, to examine the advertisements of food, drugs and cosmetics and to call the advertiser to hearings when the Secretary thinks they are false, to dispose of such matters by warnings or otherwise, if he thinks that is sufficient, or otherwise to refer them to the Commission.

Advertising has an essential place in the modern merchandising of food, drugs, and cosmetics. The advertiser should not be compelled to face a criminal prosecution and be publicly branded as a false advertiser because of a difference in opinion or in fact between him and the administrator when the difference is largely technical, academic, or literal. It is desired to prevent false and misleading advertisements but certainly it is not desired—particularly when the public health is not involved—to subject reputable persons and corporations to unjust and unwarranted criminal prosecution, based perhaps on erroneous or academic administrative decisions of violation. It is one thing to enjoin the advertiser from such advertisements, and quite another to subject him to criminal prosecution, branding him as a false advertiser and prejudicing him before the public by the very fact of prosecution, regardless of the ultimate outcome of the prosecution.

The consuming public obtains no injunctive relief from punitive procedure. It is just a case of guilty or not guilty. There is no res adjudicata. There is no precedent. Criminal courts do not write opinions which may be used in subsequent cases. The orders and stipulations of the Federal Trade Commission are informative precedents.

CONCLUSION

In conclusion, I repeat that we desire effective legislation to prevent adulteration, misbranding, and false advertising. We desire it on behalf of the public. We desire it on behalf of industry. We believe that legislation to be effective must be practicable in its application. To that end, and for that purpose, we have offered these criticisms of S. 5 in the hope that legislation will evolve which states the obligations of industry clearly, defines the prohibited acts definitely, and assures to those accused of violating it a trial in judicial tribunals.

BRIEF OF JAMES F. HOGE OF ROGERS, RAMSAY & HOGE, OF THE NEW YORK BAR, REPRESENTING THE PROPRIETARY ASSOCIATION, THE MEMBERSHIP OF WHICH CONSISTS OF SEVERAL HUNDRED MANUFACTURERS OF MEDICINAL AND TOILET PREPARATIONS

They are manufacturers of approximately 80 percent, in volume, of the proprietary products sold in the United States. Most of them are advertisers. Some are among the largest. Their products include many of the best known trade marks and names in the country.

I also represent numerous individual companies which manufacture medicinal and toilet preparations and for which my law firm has been general counsel for numerous years.

Those for whom I appear recognize that improved food and drug legislation is required in the interest of the public and in the interest of legitimate industry, holding that the interests of each are interrelated. They further take the position that manufacturers and distributors of drugs and medicinal preparations, indicated as they are for vital human needs and affecting the public health, must assume the burden of using extraordinary care in maintaining high standards of quality and in determining the truth of claims made for their products; that claims should be stated in clear terms that are not likely to mislead; that manufacturers and distributors, and not the public, must assume the risk of their ignorance or mistake.

Their views in these respects have been publicly stated and their position on specific provisions for improved food and drug legislation has taken the form of endorsement of a bill introduced in the House of Representatives by Mr. Mead, of New York, identified as H. R. 3972. I refer to that bill as a definite proposal for legislation and as a declaration of the affirmative position which these manufacturers hold on this subject.

The fact that they are for the Mead bill does not imply that they are opposed to S. 5. They have objections to S. 5. But their objections are to form and specific provisions, rather than to improved legislation and to the purposes of S. 5 in that respect.

FORM

The form of the legislation is not the most essential feature. It is, however, important. Our position on that is more a preference than an objection. S. 5, although spoken of as a revision of the existing Food and Drugs Act, is not that, as to form, because it repeals entirely the existing law.

The Mead bill, on the other hand, is drawn to overcome defects in the existing law. It does not represent piecemeal amendment, but revision. While changing the sequence of the existing law, it retains what is effective and replaces what is defective.

This form for legislation has the advantages of maintaining provisions that are familiar to all the interests affected by it, preserving court decisions that have been rendered since 1906, and maintaining uniformity that now exists between Federal and State legislation. Many States have food and drug laws modeled on the existing Federal law. In many States the Federal regulations are adopted insofar as applicable.

In addition to decisions by Federal courts construing the Federal act, there have been decisions by State courts construing their respective acts. Revision, therefore, preserves, as to the portion of the existing law preserved, the court decisions and the existing uniformity, and also affords a more likely opportunity for State laws being revised in the same respects as the Federal law is revised.

OBJECTIONS

Our objections to S. 5 are principally to administrative provisions. We have objection to some of the definitive provisions, although most of our objections in those respects fall under the subject of regulations in that our objection goes not necessarily to the prohibited act but to the provision that the secretary may enlarge upon it by regulations.

REGULATIONS

It is recognized, of course, that there are circumstances in which the Secretary should have authority to make regulations. That is recognized in the existing law. He must make administrative regulations on procedure, exemptions, tolerances, and, in a few instances, minimum standards. But, by and large, it

is possible to state the offenses and the obligations in the law rather than provide that the Secretary may state them in regulations.

I shall discuss only those regulations which affect the manufacturers for whom I appear.

1. Section 402 (d), page 16, states that a drug shall be misbranded if it is for internal use by man and contains any of a list of stated narcotic or hypnotic substances, as well as (lines 13–16) "Any other narcotic or hypnotic substance which has been designated as habit forming by regulations", and does not bear the name and quantity or proportion of such substance or derivative, and in juxtaposition therewith the statement "Warning—May be habit forming."

There is no objection to the declaration on the label of the name and quantity or proportion of any of the substances named in the section. The only objection is to the provision in lines 13 to 16 that any other narcotic or hypnotic substance which has been designated as habit forming by regulations shall be declared on the label with the statement, "Warning—May be habit forming." We suggest that in lines 13 to 16 the following language be deleted:

"Or any other narcotic or hypnotic substance which has been designated as habit forming by regulations as provided by sections 701 and 703."

2. Section 402 (f) (2), page 17, provides that a drug shall be misbranded if it does not state plainly and conspicuously on its labeling "such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 708, against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application."

It seems to us that the provision is unnecessary in view of the provision that a drug shall be adulterated—or misbranded as we suggest—if it is dangerous to health under the conditions of use prescribed in the labeling thereof and of the provision requiring adequate directions for use. However, if it is desired to have some such provision in the law, then we suggest that section 402 (f) (2) read as follows:

"Such warnings in such manner and form as may be adequate against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health, or against unsafe dosage or methods or duration of administration or application."

3. Section 402 (h), page 18, provides that a drug shall be misbranded "if it has been designated by regulations, as provided by sections 701 and 703, as a drug liable to deterioration, and is not packaged in such form or manner, or its label fails to bear a statement of such precautions, as such regulations require for the protection of public health."

We suggest that the section read:

"If it is a drug liable to deterioration and is not packaged in such form or manner, or its label fails to bear a statement of such precautions as may be adequate for the protection of public health."

4. Section 601 (b), page 24, provides that any advertisement of a drug representing it to have any therapeutic effect in the treatment of certain-named diseases, "as well as any other disease perilous to the life of the individual or to the public health which may be added to this list by regulations as provided by sections 701 and 703", shall be deemed to be false. There is no objection to the section insofar as the named diseases are concerned. The only objection is to the provision that the list may be added to by regulation, and we suggest the deletion of lines 12 to 14, including the words, "as well as any other disease perilous to the life of the individual or to the public health which may be added to this list by regulations as provided by sections 701 and 703."

Certain committees are set up to approve the Secretary's proposed regulations (sec. 703, p. 27). The committee which is to deal with drugs expressly must not include any person who has a financial interest in the manufacture, advertising, or sale of any drug (sec. 703 (e) p. 30, lines 7 to 12). If the committee is to be retained, we respectfully suggest that the Committee on Public Health include at least one, and possibly two, members who do have a financial interest in the manufacture, advertising, or sale of drugs.

There is no requirement that the committees meet in session and conduct hearings. It is merely provided (sec. 703 (f), p. 30) that the Secretary shall send to the committees transcripts of the hearings held by him. If the committees are to be retained, we respectfully suggest that the members of the committees be required to sit with the Secretary at the hearings, for even if one takes the time and pains to study the transcripts of the hearings, he is not likely to have the understanding of the subject that personal presence would beget.

The objection to laws which leave definitive provisions to be stated in regulations is not overcome by committees. In practice, the objection is, instead, emphasized. The evil is in the delegation of legislative power.

Such regulations as are authorized in the Mead bill (sec. 13) would be made by the Secretary. That is the way the existing law has it now. Under that system the Secretary is responsible for his regulations. He cannot shift the responsibility to a committee. He, rather, has to answer for the soundness and justness of his regulations.

DEFINITIVE OBJECTIONS

Other than those mentioned under the subject of regulations, we have objections to the following definitive provisions:

1. Section 401 (a) (1) provides (p. 13, lines 7–8) that a drug shall be deemed to be adulterated "if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof."

Our objection to this provision is that it is included in the section dealing with adulteration. Adulteration is not effected by the labeling or advertising, and we respectfully suggest that the provision be stricken in section 401 and transferred to section 402, dealing with misbranded drugs.

The importance of this is in connection with seizures, and the suggestion which we shall make presently that there should be no limitation upon the number of seizures as to adulteration and that there should be limitation upon the number of seizures that can be made, without court order, in the case of misbranding. Thus it is important to have this provision under "misbranding." Obviously, it is only a matter of labeling or branding for if the labeling or advertising is corrected the offense is overcome. The drug is not adulterated. It is only the branding or the labeling that offends.

The same provision appears in section 501 (a), pages 20 and 21, as to cosmetics. We make the same suggestion in that connection that the references to the labeling and advertising be stricken in section 501 (a) and transferred to section 502 dealing with misbranding of cosmetics.

2. Section 402 (a) provides (p. 15, lines 11–15) that any representation concerning any effect of a drug shall be deemed to be false if "in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion."

It would be quite impossible often to sustain representations in every particular by opinion, because opinion is not absolute and constant. Likewise, while the distinction in the dictionary is not great between the words "sustain" and "support", we believe that in law there is a distinction and that it is possible to support a representation by opinion, when it would not be possible to sustain by opinion. Furthermore, the phrase "medical opinion", as defined in section 201 (k), page 3, seemingly excludes pharmacologists, physiologists, bacteriologists, and pharmaceutical chemists. The opinion of these latter named scientists is often more important than the opinion of physicians on the effect of drugs, and we respectfully suggest that the provision should read as follows:

"Any representation concerning any effect of a drug shall be deemed to be false if such representation is not supported by demonstrable scientific facts or substantial medical or scientific opinion."

3. This same provision appears in section 601 (a), page 24, lines 1 to 5, with respect to the advertising of drugs and we make the same suggestion as respects that section.

4. We believe that, from the standpoint of public health, the misbranding sections on food, drugs, and cosmetics—particularly drugs—should provide that an article is misbranded "if it bear a copy, counterfeit, or colorable imitation of the trade mark, label, or identifying name or device of another person."

In our practice with infringements of trade marks, counterfeiting, and other forms of passing off, we have found that many potent drugs are sold under copies, counterfeits, or colorable imitations of the trade marks or identifying names of reputable and well-known products. It has therefore seemed advisable to us to have such a provision included in a law of this kind and we respectfully suggest the inclusion.

In view of the far-reaching provisions on misbranding and advertising, and of the criminal aspects, we suggest that in the misbranding and advertising sections dealing with food, drugs, and cosmetics there be added a section which provides as follows:

"When construing and enforcing the provisions of this act reasonable allowances, consistent with the purposes of the act, shall be made for (1) abnormal individual reactions to food, drugs, and cosmetics, and (2) harmless trade claims recognized by and under the common law."

SEIZURES

S. 5 provides (sec. 711 (a), p. 41) that any article that is adulterated or misbranded may be seized while in interstate commerce or at any time thereafter by libel, and further, that if a chief of station or other employee, designated by the Secretary, has probable cause to believe that the article is so adulterated as to be imminently dangerous to health, then such chief of station or employee may seize the article without any legal process whatever. All he must do is report what he has done, after he has done it, to the United States attorney who will then go through the formalities of preparing a libel.

Of great importance in this connection is the provision that a drug and cosmetic are deemed to be adulterated if they are dangerous to health under the conditions of use prescribed in the labeling or in the advertising. Of course, for administrative purposes, that means if the official or employee thinks they are dangerous under those conditions. And, so, an employee may seize food, drugs, and cosmetics without any legal process when he has probable cause to believe that they are so adulterated as to be imminently dangerous to health.

S. 5 next provides (sec. 711 (e), p. 45) that when there have been multiple seizures in which the same issues of adulteration or misbranding are raised, the claimant of the goods, by making what is called a "seasonable demand", may have all the cases tried in the court where one of the seizures is pending which is nearest to the claimant's place of business. All the cases must be tried and separate verdicts rendered in each. In other words, if the goods of a manufacturer who resides in Pennsylvania are seized numerous times along the Pacific coast, he may, if he make an application "seasonably", have the court in the district on the Pacific coast nearest to the State of Pennsylvania try all the cases.

We suggest that the case should be removed to a jurisdiction of reasonable proximity to the manufacturer's residence. Thus, if one lives in Philadelphia and his goods are seized on the Pacific coast, the case should be removed for trial to Trenton, or Baltimore, or some other place of reasonable proximity.

Sec. 711 (g) (p. 46) provides that the courts are vested with jurisdiction to restrain by injunction any multiplicity of seizures. That, however, is not an assurance against multiple seizures which can be made simultaneously. Suppose, for instance, that 12 seizures are made at the same time. Then the only effect and utility of that provision will be to authorize the courts to enjoin any more.

The bill, therefore, authorizes multiple seizures not only for adulteration but for misbranding. There is no limit prescribed upon the number of seizures that can be made for either. The only ostensible limitation is the statement just referred to that the courts may, if the petitioner is successful in his application to the courts, enjoin any multiplicity of proceedings. And, the petition to the courts will not, and cannot, be made until after the seizures have been made.

In contrast to all of this, the Mead bill provides (sec. 17)—and we suggest that S. 5 provide—that there shall be no limitation upon the number of seizures as to adulteration, but that not more than one seizure shall be made in cases of misbranding and that the single seizure may be removed for trial to a district of reasonable proximity to the residence of the manufacturer. Seizures often are made hundreds, and sometimes thousands, of miles from the manufacturer's residence.

To meet possible emergencies, the bill should further provide that in the event any article seized in the single seizure action is misbranded in manner rendering it imminently dangerous to health, the Secretary, on order of court, may be authorized to make seizures of the product so labeled which already is on the market.

Now, the effect of these suggestions is simply to secure the manufacturer against the exercise of extraordinary procedure until he has at least had a chance to appear before an impartial court. It requires only hours, and at the most, days, to bring on a hearing for an order, and it is little enough to ask that before a manufacturer's goods are to be seized in many parts of the United States because of a difference of opinion between the manufacturer and the bureau officials as to whether the product is misbranded or not, the manufacturer be allowed to protest the threatened action before a court and let the court decide whether the alleged violation is such as to justify extraordinary procedure.

No consideration is asked for goods that are adulterated. In most cases, adulteration can be definitely determined, and goods that are adulterated should be removed from commerce immediately.

Misbranding, however, is usually a matter of judgment. One person's view of what amounts to misbranding often differs from another person's view. To empower the enforcement officer to seize, or to cause to be seized, goods which he considers misbranded, forestalls the manufacturer's right to an adjudication of the differences in opinion or issues of fact which may exist between him and the enforcement officer.

We, therefore, respectfully request that the seizure section of S. 5 (sec. 711) be conformed to section 17 of the Mead bill, or, failing that, that section 711 of S. 5 be changed and amended to provide that seizure for misbranding be limited to a single seizure action, except in cases where the misbranding is dangerous to health and that, in that event, multiple seizures be made only on court order with proviso that the action may be tried in a jurisdiction of reasonable proximity to the residence of the manufacturer, distributor, or other claimant of the article seized, as for instance:

Amended to provide that seizure for misbranding be limited to a single-seizure action, except in cases where the misbranding is dangerous to health and that, in that event, multiple seizures be made only on court order with proviso that the action may be tried in a jurisdiction of reasonable proximity to the residence of the manufacturer, distributor, or other claimant of the article seized—as, for instance:

Amend section 711 (a) of S. 5 by adding on page 42, line 9, the following:

"*Provided, however,* That not more than one seizure action shall be instituted in cases of alleged misbranding except upon order to show cause, and then upon a showing by the Secretary that such article is misbranded in manner or degree as to render such article imminently dangerous to health, or that such alleged misbranding has been the basis of a prior judgment in favor of the United States in a criminal prosecution or libel for condemnation proceeding respecting such articles under this Act; and provided further, that said single seizure action shall, on motion, be removed for trial to a jurisdiction of reasonable proximity to the residence of the claimant of such article."

Amend section 711 (e) of S. 5 by striking out the italicized langauge in lines 2–14, inclusive, on page 45, and inserting in lieu thereof the following:

"In cases of articles of food, drugs or cosmetics seized under the provisions of this section when the same issues of adulteration or misbranding under the provisions of this act, raised by the same claimant, are pending in various jurisdictions, the cases, on application of the claimant, seasonably made, shall be removed for trial to a jurisdiction of reasonable proximity to the residence of the claimant. Separate verdicts shall be rendered in each case and judgments entered on such verdicts in conformity with the provisions of this section."

INSPECTION

S. 5 (sec. 707 (a), p. 32) authorizes officers or employees of the Department of Agriculture, who have been designated by the Secretary to inspect any factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment, or to enter any vehicle being used to transport food, drugs, or cosmetics in interstate commerce, and to inspect such factory, warehouse, establishment, or vehicle and all equipment, finished and unfinished material, containers, and labels there used or stored.

The courts are authorized (sec. 707 (b), p. 33) to restrain by injunction the shipment in interstate commerce, or the delivery after receipt in interstate commerce, of any food, drug, or cosmetic from any factory or establishment the owner or operator of which has denied permission to inspect. The objection to this provision is that it authorizes the courts to enjoin the shipment of goods whether they are adulterated or misbranded or not. It makes no allowances for the circumstances under which refusal to enter and inspect may have been made.

The Mead bill, on the other hand provides (sec. 19) that if it cannot be determined by an examination of a food, drug, or cosmetic after it has entered commerce whether it is adulterated or misbranded, and if permission to inspect is refused, the courts are authorized to grant an order compelling an inspection. The difference is that if the manufacturer denies permission to inspect under S. 5, whether justified in the denial or not, the courts are authorized to enjoin shipment of the goods whether they are adulterated or misbranded or not, while under the Mead bill inspection is authorized only if it cannot be determined after an article has entered interstate commerce whether it is adulterated or not, and then, in the event of refusal, the courts are authorized to compel inspection rather than enjoin shipment.

We, therefore, respectfully request that section 707 of S. 5 be amended to conform to section 19 (a) of the Mead bill, or failing that, that section 707 (b) be amended to read:

"In order adequately to protect public health and welfare, the several district courts of the United States are hereby vested with jurisdiction to restrain by injunction, temporary or permanent, any refusal of permission to inspect such factory, warehouse, or establishment in which food, drugs, or cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce, or are held after such shipment, or any vehicle being used to transport such food, drugs, or cosmetics in interstate commerce, and all equipment, finished and unfinished materials, containers, and labels there used or stored. Violations of any injunction issued pursuant to this paragraph may be summarily tried and punished by the court as a contempt. Such contempt proceeding may be instituted by order of the court or by the filing of an information by the United States attorney."

ADVERTISING

Our position on advertising is that it should be administered by the Federal Trade Commission. It is not a matter of transferring the control of advertising *to* the Federal Trade Commission. It is a question of transferring the control *from* the Federal Trade Commission. Advertising is there now. The Mead bill, which we have endorsed, proposes that the jurisdiction and powers of the Federal Trade Commission be enlarged to cover advertising which is false or misleading, for all the purposes of this legislation, and to make unnecessary any showing by the Commission that such advertising is an unfair method of competition. Thus the Raladam case mentioned here and elsewhere to the prejudice of the suggestion and the limitation upon the Federal Trade Commission's jurisdiction would be of no further consequence.

Advertising presents a serious problem. If we were concerned only with advertisements which were false in the ordinary meaning of the word, or if we were concerned only with offenders who were deliberate and malicious, there would be no problem. But, for every advertisement which is deliberately and maliciously false, we will be concerned with hundreds of advertisements that are not deliberately false and with advertisers who do not deliberately falsify.

We have no objection to criminal prosecution of false advertisements when the public health is involved. But, under this proposed legislation there will be many advertisements alleged to be false or misleading within the definitions and purposes of this legislation which do not immediately affect the public health.

We question the soundness of legislation that makes such offenses criminal and affords the opportunity for corporations and persons who are not criminally inclined being prosecuted in criminal courts with the stigma and embarrassment necessarily incurring from such prosecution.

That is the basis for our position on the matter of the Federal Trade Commission handling advertisements. That procedure is of a civil nature, an order to cease and desist, with the punishment for violation of the cease and desist order as in contempt of court. That is a serious punishment. We have no objection to injunction against false and misleading advertisements. And, as above stated, we have no objection to criminal prosecution in the case of advertisements which involve the public health. We suggest that in the section of S. 5 dealing with misbranded food there be added a section similar to section 401 (a) (1) which we have already suggested be transferred from the section on adulteration to the sections on misbranding as to drugs and cosmetics providing that the article be misbranded.

"If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof." And that in lieu of the criminal prohibitions as provided in sections 708 (a) (4) and (5), (pp. 34 and 35), there be inserted the provisions of section 5 of the Mead bill, providing that false advertisements generally be referred by the Secretary to the Federal Trade Commission; that the Secretary be granted the authority, just as the Mead bill grants such authority under section 14, to examine the advertisements of food, drugs, and cosmetics and to call the advertiser to hearings when the Secretary thinks they are false, to dispose of such matters by warnings or otherwise, if he thinks that is sufficient, or otherwise to refer them to the Commission.

Advertising has an essential place in the modern merchandising of food, drugs, and cosmetics. The advertiser should not be compelled to face a criminal prosecution and be publicly branded as a false advertiser because of a difference of

opinion or in fact between him and the administrator when the difference is largely technical, academic, or literal. It is desired to prevent false and misleading advertisements but certainly it is not desired, particularly when the public health is not involved, to subject reputable persons and corporations to unjust and unwarranted criminal prosecution, based perhaps on erroneous or academic administrative decisions of violation. It is one thing to enjoin the advertiser from such advertisements, and quite another to subject him to criminal prosecution, branding him as a false advertiser and prejudicing him before the public by the very fact of prosecution, regardless of the ultimate outcome of the prosecution.

The consuming public obtains no injunctive relief from punitive procedure. It is just a case of guilty or not guilty. There is no res judicata. There is no precedent. Criminal courts do not write opinions which may be used in subsequent cases. The orders and stipulations of the Federal Trade Commission are informative precedents.

CONCLUSION

In conclusion, I repeat that we desire effective legislation to prevent adulteration, misbranding, and false advertising. We desire it on behalf of the public. We desire it on behalf of industry. We believe that legislation to be effective must be practicable in its application. To that end, and for that purpose, we have offered these criticisms of S. 5 in the hope that legislation will evolve which states the obligations of industry clearly, defines the prohibited acts definitely, and assures to those accused of violating it a trial in judicial tribunals.

(Here was presented exhibit A being H. R. 3972 a bill introduced by Congressman Mead of New York.)

Senator CLARK. Mr. Benjamin C. Marsh.

STATEMENT OF BENJAMIN C. MARSH, EXECUTIVE SECRETARY, THE PEOPLES LOBBY

Mr. MARSH. My name is Benjamin C. Marsh. I appear on behalf of the Peoples Lobby, with offices here. I am glad Senator Copeland is here, because I am going to base my opposition to this bill on something Senator Copeland himself said in the hearing on the bill which he introduced here last year.

I raised the point there as to the impossibility and impracticability of a bill such as his previous bill, and this bill, which is sort of an autopsy, a post-mortem effort to save people from the results of profiteers in misbranded goods and in poisonous drugs. I made this statement, that there is no possibility of having an honest pure-food and drug bill unless it is positively affirmative, similar to the law relating to meats, so that the Government has to pass upon all these things that are covered by the Senator's present pure food and drugs bill, S. 5. Senator Copeland will recall that he admitted that was correct. It is in the record. I bring it up because he has committed the same offense again this year. He said it was not practical.

I asked him the question then, and I ask it now: Is it not true the Democratic party is in complete control of all branches of government? It is. And I hope Senator Copeland, on the time of the Fleischmann's yeast manufacturers——

Senator CLARK. Now, Mr. Marsh, let me advise you that any comments you have to make on the bill will be received by the committee, but personalities about members of the Senate, or anybody else, will not be received now or at any other time by any committee of which I am chairman.

Mr. MARSH. This is not personalities, and I am very sorry if skins are so thin that they cannot stand facts. We ought to have some of what you may call "curatives" for thin skins, which are advertised.

I would suggest that someone state what powers of the profiteering interests prevent the Democratic Party from drafting a bill to protect the consumers of America.

I am going to suggest—and following me I believe comes Mr. J. B. Mathews, of the Consumers Research—I am going to suggest to Huey Long that he make a speech on why the Democratic Party is afraid to protect the consumers. I think it would be a revelation which would out-Farley Farley.

I would like to ask the question, Why don't you do the thing you say ought to be done to protect the public?

I have no further statement to make. Anything such as this bill is a swindle and a farce on the American public. I am glad that this subcommittee is going to have the opportunity to report that fact back to the full committee and instruct somebody in the committee to draft an honest pure food and drugs act.

Any question will be cheerfully answered, more cheerfully than asked.

Senator CLARK. Mr. Hanson.

STATEMENT OF ELISHA HANSON, ATTORNEY, AMERICAN NEWSPAPER PUBLISHERS ASSOCIATION

Mr. HANSON. Mr. Chairman and gentlemen of the committee, I have a very short prepared statement which I shall ask the privilege of submitting in the record, as it will undoubtedly conserve your time to have it done that way.

Senator CLARK. That may be done.

Mr. HANSON. I do, however, wish to state that I am the attorney for the American Newspaper Publishers Association, the membership of which is made up of more than 400 daily newspapers published in the United States. The association has been in existence for nearly 50 years, and during the entire period of its existence it has carried on a campaign within its own ranks to drive out false and fraudulent advertising from the columns of newspapers of this country. It has no sympathy whatsoever with false and fraudulent advertising, and it wishes to ask no privilege for anyone willfully guilty of false or fraudulent advertising.

The association has given consideration to this bill, and it has set forth certain of its objections to the measure in the memorandum which I will file with you.

Now, it occurs to us, to summarize, that, insofar as false and fraudulent advertising are concerned today, there is ample law on the statutes to take care of those offenses, whether they be in interstate commerce or whether they be in intrastate commerce. If there is any injury to the public through any false or fraudulent advertisement which appears in the newspaper and which calls for any use of the United States mails whatsoever, section 2350 of the postal statutes provides a very severe penalty therefor.

Also, if, one who, engaged in the sale of food, drugs, or cosmetics, inserts an advertisement in a newspaper which goes through the mails, is subject to the penalty of that statute if that advertisement is false or fraudulent. If there be any use of the mails for an order, the statute is there and it is ready to be enforced.

On the other hand, the Federal Trade Commission has jurisdiction over unfair acts of competition. There is a question in some people's minds as to whether it has jurisdiction under the existing statutes over advertisements, but I want to say that, as the attorney for the American Newspaper Publishers Association over a period of 10 years, no newspaper has ever contested the efforts of the Federal Trade Commission to drive out false and fraudulent advertising from our columns for our businesses.

Now, just for example, I came to my office this morning, after being away for a day, and in the morning mail I found four notices of actions taken by the Federal Trade Commission where respondents have stipulated that they will cease false and fraudulent advertising. The procedure in each one of those cases has been that if a newspaper were involved, the Federal Trade Commission would make that newspaper a party to the proceeding, and in all such cases the newspaper stipulates itself out of the proceeding by agreeing that it will abide by the decision of the Commission.

There has been the utmost cooperation between the daily newspapers of this country and the Commission in its effort to drive out false and fraudulent advertising as an unfair competitive practice, and, as I have pointed out, insofar as the public is concerned, in my opinion the postal statute, if it were enforced, and I make no statement that it has not been properly enforced because I am not advised of the facts, contains full authority to drive out false and fraudulent advertising that affects the public but does not affect a competitor.

Now, I do want you to give serious consideration to the definition of "advertisement" in the bill. I think it is extremely loose. The purpose of an advertisement is to create an interest in the thing that is advertised, to create possibly a demand for the article advertised, if it be an article, or to create an interest in the idea, because frequently ideas are advertised, and I have suggested that your definition of an advertisement to be changed to read:

> The term "advertisement" includes representations of fact or opinion disseminated to the public in any manner or by any means for the purpose of creating an interest in or a demand for food, drugs, or cosmetics.

In other words, I do not try to give you a broad definition of an advertisement for all things but confine it simply to this bill.

There is another provision in the bill to which I wish to call your attention specifically, and that is the provision in section 708 which would impose a criminal penalty on one who published an advertisement for an advertiser and then refuses to give information to an agent of the Government who comes into his office. I submit that this Congress should not start or inaugurate a policy whereby if some agent of the United States Government wants to go on a fishing expedition in this business, or any other business, and does not get all the information he wants, that fact can be certified to a court with the resultant fine and imprisonment. I have moved or suggested that that entire paragraph be stricken from this bill.

Senator COPELAND. That is all of section 708?

Mr. HANSON. I will point out what it is, sir. At page 37, line 22, striking out all in that subsection (d), beginning with "It shall be unlawful for any publisher" and so forth, down through line 10 on page 38.

Advertising contracts are usually entered into between publishers and agencies on the matters that are nationally advertised, articles that are nationally advertised. Of course there are many contracts entered into between publishers and individuals, but under the postal acts all you need to do is to subpena the publisher. Under the Federal Trade Commission Act, all you need to do is to make the publisher a party to the proceeding and then you can follow due process of law and get the information required. But the section goes further on and provides if they do not give the information to an administrative official they are automatically subject to jail sentence or fine or both, and we think that that is an offensive provision and shold be eliminated, that no such policy should be put into law.

Thank you very much gentlemen.

BRIEF OF ELISHA HANSON, ATTORNEY FOR THE AMERICAN NEWSPAPER PUBLISHERS ASSOCIATION.

Mr. Chairman and members of the committee, my name is Elisha Hanson. I am an attorney, with offices at 729 Fifteenth Street, NW., Washington, D. C. I appear before you in behalf of the American Newspaper Publishers Association to present the views of that association in respect of the measure under consideration. The bill which I shall discuss is Committee Print No. 3, published on February 14, which I presume is the third and final revision of S. 5 introduced on January 4 by Senator Copeland of New York.

The American Newspaper Publishers Association has within its membership more than 400 publishers of daily and/or Sunday newspapers. In addition, the association works in close cooperation with the five great regional associations of daily newspaper publishers, and also with numerous State associations of daily newspaper publishers.

The interest of the association and of newspaper publishers generally is not that of a manufacturer or a distributor of articles coming within the purview of this measure. However, daily and Sunday newspapers comprise the most extensively used advertising medium in the United States, so naturally any measure which affects advertising, whether it be to restrict or to increase advertising, or to place penalties on advertising, including the severe penalties of fine and imprisonment on those who publish the advertising in behalf of others, is a matter of vital interest to publishers.

Let me say at the outset that the association for which I speak does not approve of false or fraudulent advertising—it wants none of it—and for more than 40 years its membership as constantly and unflinchingly opposed false and fraudulent advertising.

Let me also state, however, in order that there may be no misconception, that the association has given very careful consideration to this measure now before you, and is opposed to the measure as it stands, for the reasons which I shall present.

Assuming, for the purpose of argument, that the present Federal Food and Drugs Act should be strengthened, then the question before you is, How best to strengthen it? If it be your purpose to permit the manufacture and sale of foods, drugs, and cosmetics which are not injurious to the public health, and which are of benefit to the public generally, then in my opinion if you should approve of this measure you will defeat your own purpose.

Some years ago a distinguished justice of the Supreme Court said it was not what one did in life that was the important thing, but the way in which he did it. This measure is so filled with extreme penalties that, if enacted into law, it undoubtedly will serve materially to reduce the business incident to the manufacture and distribution of all foods, drugs, and cosmetics of the best kind and description, whereas I understand it to be the purpose of its sponsors only to prevent the manufacture and distribution of adulterated and injurious products.

I shall now call to your attention certain specific objections to the measure. On page 3, under subsection (j) of section 201, there is a definition of the term "advertisement" which is, in my opinion, too loose. The purpose of an advertisement is merely an effort to create interest in the thing advertised. It may promote a demand for the product or the idea, but it does not directly, as a rule, result in a sale. Therefore, while I dislike to suggest the substitution of a defi-

nition of my own for that of someone else, I do submit for your consideration the following for the definition included in lines 14, 15, and 16 on page 3:

"The term 'advertisement' includes representations of fact or opinion disseminated to the public in any manner, or by any means, for the purpose of creating an interest in or a demand for food, drugs, or cosmetics."

I realize that this definition is limited, so as to refer only to the products covered by this proposed measure, but I think the definition follows the theory of your section 201.

On page 13, chapter 4, section 401, subsection A–1, I suggest the elimination of the words "or advertising" in line 8. As I have stated, the purpose of advertising is to create an interest in and a demand for the product which is advertised. However, in the matter of the use of a drug which has been advertised, the directions on the label are what should be followed and not the directions in some circular which has been distributed prior to the purchase of the article which is to be used.

Let us assume, for the purpose of argument, that there is a conflict between the statement on the label and the representations in the advertisement. The purchaser would have the package containing the product before him at the moment of use, and undoubtedly would look at the label for instructions rather than to some advertising material which he had read prior to purchase.

On page 21, line 2, I suggest the elimination of the words "or advertising" in section 501, subsection (a), for the same reason.

I next suggest the elimination of part of subsection (d) of section 708, beginning with the words "it shall be" on line 22 of page 37, and running down through line 10 on page 38.

This is one of the most offensive provisions of this bill. It provides an extreme penalty for the refusal by a publisher of information requested by an officer or an employee of an administrative department of the Government. There is nothing like it that I have been able to find in any particular law, and when read in consideration with the provisions of section 709, subsections (a) and (b) it would make it practically impossible for any publisher in the United States to accept any food, drugs or cosmetic advertising without facing squarely into the doors of a jail.

There is already ample law on the statutes to take care of any offense which relates to false advertising. The Federal Trade Commission Act makes false advertising, injurious to a competitor, illegal, and the Commission is empowered under the act creating it to prevent the dissemination of such false and fraudulent advertising.

Insofar as the general public is concerned, section 2350 of the Postal Statutes makes false advertising illegal, and subjects the person who is guilty of devising the scheme to defraud or to obtain money by means of false or fraudulent representations, to a fine of not more than $1,000 or imprisonment of not more than 5 years, or both.

The only purpose of section 708 is to compel someone to give to an administrative officer of the Government information, on the basis of which that officer can then proceed against the real party in interest. There is ample judicial process to accomplish this purpose at the present time without any such provisions, and the whole theory of this paragraph is offensive to the American theory of due process of law.

If the Secretary of Agriculture has cause to believe that an advertisement which has been published in a newspaper is false or fraudulent, insofar as its representations of the value of a food, drug or cosmetic are concerned, he can start his proceedings in the court, under the Postal Statutes, he can subpena the publisher of the newspaper or the distributor of the advertising, or the owner of the radio broadcasting station which has disseminated the information, and compel the giving up of any information which this paragraph requires, without any difficulty.

There is no occasion to give to the Secretary of Agriculture, or any other administrative official of the Government, the power to certify to a court that a newspaper publisher has refused to give him certain information which he has requested, and thereby automatically impose upon that court the duty of fining and/or imprisoning the publisher of a newspaper.

Many newspapers are published by persons in their individual capacity, and others are published by corporations, yet under the provisions of section 709 (a), if the employee of an individual publisher refuses to give the information sought by the Secretary, then the publisher is held subject to the penalties of section 708 (d), and under the provisions of 709 (b), if the employee of a corporation declines to give the Secretary the information sought, then the directors and officers and/or agents of the corporation are held subject to the penalties of section 708 (d).

I particularly want to call your attention to the fact that if there are the abuses which the proponents of this bill suggest, if they have existed for years, as has been represented, then certainly someone in the Government is at fault for not having proceeded under section 2350 of the Postal Statutes, which now contains ample authority to wipe out such abuses.

It is impossible to conceive of anyone's carrying on a business in interstate commerce in the sale of foods, drugs, and cosmetics, without the use of the mails, and under this section of the statutes, if it were vigorously enforced, it would be impossible for anyone to carry on a business in interstate commerce which in any way would be injurious to the public health. I make this statement advisedly, without respect to the fact as to whether the products so manufactured and distributed are banned by the present act. The mere fact that they are falsely advertised, if it can be proved, would bring those who distribute them within the purview of this law.

On the general question of advertising and its relation to interstate commerce, I wish to call your attention to two comparatively recent decisions of the United States Supreme Court. In *Blumenstock Bros.* v. *Curtis Publishing Co.* (252 U. S. 436), the Court, through Mr. Justice Day, stated that advertising contracts did not involve any movement of goods or merchandise in interstate commerce, or any transmission of intelligence in such commerce. In other words, the Court held than an advertising contract had but a remote effect upon the interstate commerce of the commodity advertised.

In another case decided by the Supreme Court, that of *Moore* v. *The New York Cotton Exchange et al* (270 U. S. 593), the question was that affecting operations on the New York Cotton Exchange, where the members of the exchange dealt in contracts for the purchase and sale of cotton for future delivery. The Court said, in respect to this:

"If interstate shipments are actually made, it is not because of any contractual obligation to that effect; but it is a chance happening which cannot have the effect of converting these purely local agreements, or the transactions to which they relate, into subjects of interstate commerce. The most that can be said is that the agreements are likely to give rise to interstate shipments. This is not enough."

Now, the most that can be said of any advertising—whether it be of foods, drugs, cosmetics, or any other products—is that the advertising may give rise to interstate shipments of the products advertised; but as the Court said in the Moore case, this is not enough to subject the advertising or the advertisements to Federal jurisdiction per se. Even so, false advertising can be stamped out through the Postal Statutes.

I want to reiterate. If, as a result of the false or fraudulent advertising of a product there is a use of the mails relating to its shipment, whether it be in interstate commerce or in intrastate commerce, section 2350 of the Postal Statutes gives ample authority to take care of that kind of a situation; and further, if the advertising is false and fraudulent, and adversely affects a competitor engaged in interstate commerce, then the Federal Trade Commission Act contains power to prevent such abuse.

Senator CLARK. The Chair desires to make part of the record a communication from the legislative committee of the Medical Society of the District of Columbia, suggesting certain amendments.

MARCH 8, 1935.

The Hon. CHAMP CLARK,
Senate Office Building, Washington, D. C.

DEAR SIR: The medical profession is well aware of the fact that certain changes should be made in the present Pure Food and Drugs Act. This applies particularly to certain drugs which have come into common use during the past few years and are, to a certain extent, habit forming, and detrimental to health when not used judiciously. The medical profession is in full accord with the principles of regulating their sale to the public. We feel that S. 5 will go a long way in such an improvement.

There are two or three minor comments and changes which, however, we feel are justified.

No place in this bill specifically exempts a prescription of the medical profession from regulations laid down in section 402 (Misbranded Drugs) (d) and (f). Such an exemption is implied in section 201 (Definition of Terms) (b) and (k).

Therefore, it is urgently recommended that the following provision be inserted at the end of paragraphs (d) and (f), section 402: "*Provided*, That nothing in this regulation shall apply to drugs prescribed by the medical profession."

Obviously it would be unfair to divulge the contents of a prescription to certain patients, and especially to append such a statement as, "Warning—May be habit forming."

The legislative committee of the Medical Society of the District of Columbia heartily endorses the provisions of this bill, except as noted above.

Respectfully,

P. A. McLENDON, M. D., *Chairman*,
JOHN MINOR, M. D.,
H. D. SHAPIRO, M. D.,
Legislative Committee.

Senator CLARK. Miss Scott.

STATEMENT OF MISS IZORA SCOTT, NATIONAL WOMAN'S CHRISTIAN TEMPERANCE UNION

Miss SCOTT. Mr. Chairman, I have a very brief statement from the National Woman's Christian Temperance Union.

My name is Miss Izora Scott. I represent the National Woman's Christian Temperance Union, and the statement refers to the provisions of the bill relating to alcohol.

The National Woman's Christian Temperance Union has been interested in the operation of the Federal Food and Drug Act since its inception in 1906. In fact, the National Woman's Christian Temperance Union was one of the organizations which cooperated with Dr. Harvey W. Wiley in campaigning for such legislation.

All during the years since 1906, we have appreciated the work done by the Food and Drug Administration of the Department of Agriculture in administering this law—teaching the consumers that they could demand honesty of labeling and purity of products, teaching business men and manufacturers that it was not only their public duty but also to their private advantage to carry out the provisions of the law as to standards of honesty and purity.

In consequence of this general appreciation, the National Woman's Christian Temperance Uuion endorsed S. 2800 at their national convention in November 1934. This endorsement was given in spite of the fact that alcohol, a subject in which they are especially interested, had been removed from the list of narcotic habit-forming drugs as found in the law of 1906 and had been placed in a separate paragraph along with so-called "stimulant-depressant substances."

Now we find in the latest committee print of S. 5, which supersedes S. 2800, that the whole paragraph on stimulant-depressants—(c) of section 8 of S. 2800—has been cut out, with the result that alcohol not only loses its classification with narcotics where we believe it properly belongs, but also loses any classification at all in the bill.

It has been suggested that the words "including any alcohol present" could be added after the last word "ingredient" in line 25, page 16, of the committee print of S. 5. To my mind, that would be the least desirable of several possible amendments, particularly since the words "quantity or proportion" have been cut out in line 24.

The amendment which we should like best would insert "alcohol" in line 9, page 16, after the colon, bringing it in harmony with the present law as written by Dr. Wiley. Our second choice would be

to reinstate paragraph (c) of section 8 of S. 2800 in which form we accepted the bill last year. The suggested change in line 25, adding the words "including any alcohol present", would be, in my opinion, the least acceptable choice of all.

Senator COPELAND. Pardon me. Let me know exactly what you have in mind.

Miss SCOTT. Page 16, line 25, the last word of the paragraph, after the word "ingredient", it has been suggested that we might add "including any alcohol present." I had several conferences with those working on this bill and the changes in it, and that suggestion was made as a possible correction or addition which might be accepted by the committee. The amendment which we should like best to insert would be to insert "alcohol" in line 9 of page 16 after the colon, bringing it in harmony with the present law as written by Dr. Wiley. Our second choice would be to reinstate paragraph (c) of section 8 of Senate bill 2800, in which form we accepted the bill last year.

The suggested change in line 25 adding the words "including any alcohol present" would, in my opinion, be the least acceptable choice of those suggested. I thank you.

Senator CLARK. Mr. Draper.

STATEMENT OF NORMAN DRAPER, INSTITUTE OF AMERICAN MEAT PACKERS OF CHICAGO

Mr. DRAPER. My name is Norman Draper and I am appearing as the representative of the Institute of American Meat Packers, of Chicago. I am the Washington representative of that organization. The Institute of American Meat Packers is the spokesman for the meat-packing industry, which is the largest manufacturing industry in the United States.

We would like to suggest a brief amendment to be inserted in this bill at some appropriate place, which would read as follows:

Provided further, That any meat or meat food product manufactured, prepared, processed, stored, handled, or labeled under the supervision of employees of the Bureau of Animal Industry of the United States Department of Agriculture, pursuant to the Act of Congress approved March 4, 1907 (34 Stat. 1260 ff., title 21, U. S. C. A., sec. 71 to 93), as amended, known as the "Meat inspection law", and the rules and regulations of the Secretary of Agriculture promulgated thereunder, shall be exempt from the provisions of this Act, but only to the extent of the application of the said Meat Inspection Act.

The reason for that is that we feel that such an amendment is extremely necessary because if this bill should pass without it, this great industry might well be placed in the position of having its plants under inspection at the same time by two different agencies of the Department of Agriculture, namely, the Bureau of Animal Industry and the Food and Drug Administration. Certainly there could be no point in doing that. Also, this would be a needless Government expense. I believe the committee will realize that when you get two different groups of inspectors from two different Government bureaus doing the same thing in the same plant, the likelihood of conflicts of opinion between the two groups is by no means a remote one.

Furthermore, without the amendment we would have two different Government agencies within the Department of Agriculture dealing with labels, and so forth. As it is, the packing industry, under the meat-inspection act, cannot even use a label unless it is approved in advance by the Bureau of Animal Industry, this in accordance with

the Meat Inspection Act and regulations thereunder. In this respect, the Meat Inspection Act goes considerably further than the present bills under consideration.

Still further, under the Meat Inspection Act, the packing industry is subjected to a far greater regulation with respect to many of its operations than would be possible under the Senator's bill; that is, S. 5. The only thing we are trying to accomplish in having our amendment included is to get away from having this industry under two separate jurisdictions where identical subjects might, and in all probability would, be involved. I shall explain that we have no fears as to what might happen in the immediate future, but what might develop 5 or 10 years from now, with a new set of officials with new ideas, each one trying to promote his own, is entirely a different matter. There have been instances in the past where we have had annoying and entirely unnecessary experiences as a result of two different branches of the Government claiming to have jurisdiction over the same thing, or trying to secure each for itself jurisdiction over the same thing. A condition of this sort can lead to nothing else except confusion both of the Government and of the industry.

Incidentally, nobody has ever had cause to complain against the packing industry for doing any of the things prohibited or regulated in the present bill, certainly none of those things covered by the meat-inspection law.

I can understand why there might be an opinion here and there that the amendment we suggest is not necessary; this is on the ground that if this amendment is included the whole act might be cluttered up with other amendments. Such expressions have been made to me. If such a view is voiced, I should like to answer it now in advance. The answer is that a dual jurisdiction over biologicals, or cosmetics or hair dye, or something of that sort, is of relatively small importance as compared with the enormous volume of the meat-packing industry, where a dispute between two different inspectors from two different bureaus might even cause a plant to suspend operations while the two gentlemen in question were getting their views reconciled. Such a suspension of operations, even for 20 minutes, in some plants, would mean a very heavy loss to the establishment, without anybody being benefited whatsoever. If there should be any doubt about that question I should like to ask the subcommittee to ask a representative of the Bureau of Animal Industry for his opinion with respect to this amendment.

Senator CLARKE. Mrs. Luckie.

STATEMENT OF MRS. S. BLAIR LUCKIE, CHAIRMAN OF LEGISLATION, GENERAL FEDERATION OF WOMEN'S CLUBS

Mrs. LUCKIE. Mr. Chairman, I have the honor of representing the General Federation of Women's Clubs. I say advisedly we are the largest organized group of women in the United States, with a paid-up membership of more than two million. We are conservative in our line of work, but articulate in anything concerning the home, the health of our children, or the development of a better condition under which we may live.

This organization of which I am speaking was largely instrumental in the passage of the so-called "Wiley bill" in 1906, and we have consecutively supported that bill in its interpretations.

At that time such a thing as cosmetics and the radio advertising was not known, but we felt we made a tremendous step in advance, and now we plead with you for the passage of this bill possibly in its entirety.

From the telegrams coming to my desk since the hearing in this room last Saturday, I can state to you that we, as an organization, are opposed to the transfer of advertising to the Federal Trade Commission. We believe that we can trust the interpretation of the advertising for the benefit of our homes and our children to the Department of Agriculture.

We believe you have made a tremendous step in advance in dividing the responsibility into two boards, as represented in your bill.

I have listened with a great deal of interest to the amendments proposed this morning in your bill for the elimination of several of the very strong points. I do not wish to have them eliminated. The only suggestion, Mr. Chairman, that I might offer, representing this greater organization, with a standard for the development of our homes, is that the word "alcohol" may be inserted in the list of habit-forming drugs. We are consistent, as a temperance organization, and we believe that alcohol is just as much a habit-forming drug as many of the drugs listed here in your bill.

I have prepared somewhat of a little talk, but you have been so wisely educated this morning that I will not trespass longer upon your courtesy.

Senator CLARK. We will be very glad to have you insert it in the record, if you care to, Mrs. Luckie.

Mrs. LUCKIE. I wish very earnestly to make the statement that when our great federation of 2 million women become articulate in any subject such as this, that is affecting our homes, they are very earnest in their endeavor.

We supported in principle Senate bill 2800. It has been made a subject of study by our great organization during the last year, so we have some intelligent conception of what Senate bill 5 is, with minor differences.

Certain technicalities in the bill possibly do not worry us as much as they do others; but we are weary, Mr. Chairman, of hearing over the radio certain drugs advertised that will cure anything from pyorrhea to chilblains. We are weary of hearing over the radio not only the therapeutic value of drugs but going to the extent of even advising the quantity or quality and the regularity. We know that we may be a gullible public, and because of that we seek protection. Thank you very much.

Senator CLARK. Thank you.

BRIEF OF MRS. S. BLAIR LUCKIE, CHAIRMAN LEGISLATION, GENERAL FEDERATION OF WOMEN'S CLUBS

The General Federation of Women's Clubs, a national organization numbering over two million women, on May 25, 1934, at its annual convention held at Hot Springs, Ark., endorsed the principles of the Administration bill to provide a new food, drug, and cosmetics law, as exemplified in bill S. 2800. The General Federation of Women's Clubs desires again to assert its stand behind the present Administration bill, namely, S. 5, Committee Print No. 3, introduced by Senator Royal S. Copeland, with such amendments as are approved by the Administration.

The General Federation of Women's Clubs opposes the idea of transferring authority to prevent false advertising, other than the label, to the Federal Trade Commission. The Federal Trade Commission was created to prevent unfair

methods of competition in commerce, and under that authority has for years had jurisdiction over false advertising wherein a manufacturer can claim unfair competition. We oppose this transfer (1) for the reason that the Federal Trade Commission would have to depend for scientific research on the Food and Drugs Administration, just as at present. There is no good reason why there should be a distinction made between advertising on the label and advertising through other media, as witness what happened to prohibition enforcement when the authority was divided between the Department of Justice and the Treasury Department. (2) And also for the further reason that the Federal Trade Commission has no punitive authority other than to issue an order to "cease and desist" and can take a manufacturer into court only when it can show its order has been violated. Protection to the public is only incidental under such an arrangement. We want enforcement of the law in the hands of the Food and Drug Administration, where it properly belongs and where it was placed in the original food law.

We strongly urge the passage of Senate bill 5, Committee Print No. 3, as amended by the administration. While we understand that this bill stands for the old McNary-Mapes amendment of the old law of July 8, 1930, which provides in section 302 (h) for the proper labeling of food below United States standard, and while this bill also provides for standards of identity, we still believe that the home makers are also entitled to those multiple standards of quality by which the buyer can relate quality to price. We realize that articles of food must be fit to eat or they would not be on the market but as home makers we desire that the label indicate the value of the article to warrant the price asked. This change can be made by striking out "a" and adding "s" to "standard" in section 302 (h), line 23, page 7, and by striking out "a reasonable" in line 3, page 10, and adding "s" to "standard." These changes will permit the Secretary under the advice of the Food Standards Committee to promulgate simplified standards such as 1, 2, 3, or A, B, C or any other easily understood nomenclature for the benefit of the buyer.

We believe that this bill, which is an evolution of the original bill, drawn up by the competent food enforcing officials, is the one best suited for the protection of the consuming public.

Senator CLARK. Mrs. Wiley.

STATEMENT OF MRS. HARVEY W. WILEY, PRESIDENT DISTRICT OF COLUMBIA FEDERATION OF WOMEN'S CLUBS

Mrs. WILEY. Mr. Chairman, my statement will be brief. The District of Columbia Federation of Women's Clubs, with a paid membership numbering 5,890 women in this city, on December 18, 1933, at a regular meeting, endorsed the principles of Senate bill 1944, introduced by Senator Royal S. Copeland and recommended its passage without substantial amendment. Since then we have done all in our power to further progress on this measure, throughout its various metamorphases, up to the present draft, namely Senate bill 5, Committee Print No. 3.

We believe in this measure because it is endorsed by officials whose sole purpose it is to protect the interests of the consuming public. In 1912 when Congress was considering, at the request of President Taft, an amendment to the Food and Drugs Act, which would cover therapeutic claims for drugs, the Department of Agriculture sponsored the Richardson bill which would have extended the Food and Drugs law to cover advertising, cosmetics, and several other features now incorporated in Senate bill no. 5, Committee Print No. 3. Dr. Wiley, who had then resigned from the position of chief chemist, appeared at the hearings to testify for the Richardson bill. He said he believed that such a bill to amend the food law could be drafted only by those who had had experience in enforcing the law and that in the light of his 6 years of experience in the enforcement of the food law, he believed that the proposed extension of authority in the Richardson bill would give immense strength to the law.

Because I agree with what Dr. Wiley said in 1912 and from my own personal knowledge of the officials of the Food and Drug Administration, what they are doing and what they have done for the consuming public. I have confidence in the measure which they support.

I wish to add this, I am in favor of the amendments proposed by Mr. Robert M. Allen, legal counsel for the American Pure Food League (1) to add on page 4, line 15, the words: "which may render it injurious to health or which" after the words "deleterious substance" so as to take care of dangerous substances prior to the determination of limits of tolerance: (2) On page 4, line 22, to change the words "have been" to "be" so as to provide that a food shall be deemed to be adulterated before and not after deaths and disease have been caused by filth and contamination; and (3) to add to page 5, at the end of section (c) on line 14:

Provided that such coal-tar color or other artificial color shall not be used in any food for the purpose or effect of deception and that such deceptive use shall not be made legal under any labeling or other provisions of this Act.

in order to give the consuming public the guarantee of the use of as much real fruit in manufactured foods as possible.

I favor the ideas expressed by Miss Izora Scott, legislative secretary of the Women's Christian Temperance Union, of which I am a member, to proclaim alcohol the public enemy, which it is, by placing it, either among the habit-forming drugs on page 16, line 9, or at the bottom of page 16, line 25, after the words "name of each active ingredient" to insert the words "including any alcohol present."

I agree with the representatives of the 11 women's organizations who spoke on March 2d that if multiple standards for canned and other foods could be provided in section 302 (h), page 7, line 23, and in section 303, page 10, line 3, by changing the word "standard" from the singular to the plural in order that home-makers can relate quality to price in their purchases, much will have been accomplished.

But in my opinion, these and all other amendments to the bill should be submitted to the scrutiny and recommendation of the Chief of the Food and Drug Administration and in the light of his 28 years of food law enforcement, should be drafted in the way best calculated, in his opinion, to protect the public.

Senator CLARK. The committee will take a recess until 1:30.

(Whereupon, at the hour of 12:15 p. m., the committee recessed until 1:30 p. m. of the same day, Friday Mar. 8, 1935.)

AFTERNOON SESSION

Senator COPELAND. Dr. Woodward, will you testify?

STATEMENT OF DR. WILLIAM C. WOODWARD, AMERICAN MEDICAL ASSOCIATION

Dr. WOODWARD. I appear as counsel for the American Medical Association. The American Medical Association is made up of approximately 100,000 physicians and is organized as a corporation not for profit. It has no interest in the purchase or sale of food, drugs, or cosmetics except that of other good citizens, in seeing that they are pure and unadulterated, and we may claim, to that extent, to appear on behalf of the consumer.

I have arranged what I have to say so as to present certain basic propositions first, leaving minor details for submission in a brief or otherwise as time may require.

In the first place, on page 2, beginning at line 5, section 201 (b), is a definition of the term "drug". On behalf of the association I must take certain exceptions to the form of that definition. It is rather difficult to define the term "drug" so as to include therapeutic appliances of all kinds, and I suggest that the two be separated.

I have prepared, and will submit in a moment, if the committee desires, language that may accomplish that purpose. If the term "drug" is to remain as it is, I should say that the language in lines 6 and 7, "and not for the regulation of the legalized practice of the healing arts," will tend only to confuse the issue. I understand that that language has been introduced to satisfy certain groups of practitioners of the healing art who fear that otherwise the act may interfere with their practices, and yet its introduction at this point seems to me to be confusing. If those practitioners require protection, protection can be better afforded by an independent section or subsection placed somewhere else in the bill reading somewhat as follows:

> Nothing in this act shall be construed as limiting the right of any legally qualified practitioner of the healing art professionally to use, advise, apply, administer, or prescribe for the prevention, diagnosis, relief, or cure of disease, defect, or injury, or disorders incident to pregnancy, anything that he is authorized by his license or registration to employ for that purpose.

We recognize, of course, as a matter of law, that this is not necessary, because the Federal Government cannot regulate the practice of medicine, but if, as an act of expediency, the men outside the regular medical profession feel they must have protection, that language seems to me to be ample to cover it.

Senator CLARK. What do you term the regular medical profession, Doctor?

Dr. WOODWARD. Men who have graduated with the degree of doctor of medicine and who are practicing independent of any dogma, who are at liberty to use any lawful method whatever for diagnosis and treatment. That is the only limitation on the regular practice of medicine.

Senator CLARK. As a matter of fact the so-called "American Medical Association" really comprises the allopathic school, doesn't it?

Dr. WOODWARD. Oh, no; there are homeopathic physicians in it. Any one who practices independent of dogma and who has the degree of doctor of medicine is eligible. It is the dogma against which we are organized.

Senator CLARK. What do you mean by "dogma"?

Dr. WOODWARD. A belief, for instance, that all diseases and ailments are due to subluxation of vertebrae, that by the replacement of the vertebrae you can cure all matter of illness.

Senator CLARK. That refers to chiropractors?

Dr. WOODWARD. Yes.

Senator CLARK. I am just interested in getting your slant on it because it has been frequently charged by the homeopath and other schools of medicine that they belong to the American Medical Association. They rather slipped under the fly of the tent like a boy sneaking into a circus. It is really an allopathic organization. I would like to have your statement on the subject.

Dr. WOODWARD. I believe the Senator from New York can say that we admit many homeopaths at the present day.

Senator CLARK. I did not mean to interrupt you, Doctor. Go ahead.

Dr. WOODWARD. The language I have given I think will protect cultists.

Senator COPELAND. That would be in the form of another definition, would it not?

Dr. WOODWARD. I would suggest that it be placed on page 39 after line 12 as a new subsection, but I do not know that that is any better place than some others.

Senator COPELAND. We had a communication this morning, at least the chairman of the committee did, from the Medical Society here about doctors' prescriptions. I wonder if that exhibit is here at the moment.

Dr. WOODWARD. I shall come to that in a minute.

Senator COPELAND. All right.

Dr. WOODWARD. If the language defining "drug" is to be retained I believe before the word "cure" in line 11 on page 2, there should be inserted the word "diagnosis", because it is quite as important that drugs used to aid in the diagnosis of disease should be as pure as those that are used for the cure of disease. Where you inject drugs, as you may have to, intravenously in order to facilitate a roentgenologic examination of the gall bladder or kidneys, you want to be sure that the drug is a pure drug.

Then, Senator Copeland, our people are very eager that the term "Homeopathic Pharmacopoeia of the United States" be eliminated. I submit that for your consideration.

Senator COPELAND. You would not consider that I would favor that, would you?

Dr. WOODWARD. The statements are made by two of our men who have special knowledge with respect to those matters; one is the director of our bureau of investigation who has been engaged for many years in the investigation and the exposure of all kinds of fraud with respect to the practice of the healing art and of medicines. Dr. Arthur J. Cramp; I asked for his opinion, and he writes:

> By making the Homeopathic Pharmocopoeia of the United States official, as the proposed bill would, it would mean that fakers could put up sugar pills and claim that they are homeopathic remedies and sell them for what the homeopaths claim certain of their preparations are good for, and there would be no way of stopping them. This has already been done in the past, but under our present law the thing was declared fraudelent.

He adds:

> A great many homeopathic remedies are quite incapable of being analyzed. That is to say, they contain nothing but milk sugar with such an infinitesimal amount of drugs as to be wholly worthless.

Dr. Paul M. Leach, the secretary of our Council on Pharmacy and Chemistry, wrote that—

> The inclusion of the Homeopathic Pharmacopoeia in the bill is sure to lead to trouble.

Senator CLARK. Does not it come back to exactly what I asked you a few minutes ago?

Dr. WOODWARD. I think not.

Senator CLARK. It seems so to me.

Dr. WOODWARD. The Homoeopathic Pharmacopoeia has not been brought up to date for many years, indicating, I think, it is not regarded as a very important item in the practice of homeopathy at the present time.

Senator CLARK. The American Medical Association disapproves of homeopathy?

Dr. WOODWARD. Not of homeopathy but of the Homoeopathic Pharmacopoeia.

Senator CLARK. That may be entirely correct. I am not expressing any opinion on that, but I am trying to get the attitude of the American Medical Association.

Dr. WOODWARD. We might add the Homoeopathic Pharmacopoeia is not included in the Food and Drugs Act of 1906. So far as I know, no one has ever been harmed by its exclusion. I think experience is a very good guide, but I shall leave that to the committee.

Senator COPELAND. Can you examine chemically or otherwise the various vaccines and serums and determine their potency by analysis?

Dr. WOODWARD. Biologically, yes; and bacteriologically. You can determine whether they are contaminated with bacteria that are injurious, and by using test animals you can measure their potency.

Senator COPELAND. You might do that with the homeopathic drug, might not you?

Dr. WOODWARD. I will defer to your opinion, Senator. We will not argue on that. You know more about that than I do.

My suggestion, however, with respect to this subsection defining drugs (201 (b)) is that it be divided into two subsections, one dealing with drugs and the other dealing with therapeutic appliances. I believe that the inclusion of devices of all kinds under the word "drug" would create some difficulty of enforcement under the law.

As the bill is now drafted, I believe that the definitions of "adulteration" and "misbranding", that apply to drugs, are not altogether apt, when we discuss devices of various kinds. I have here the draft of the suggested language which I shall be glad to either read to you or leave with the committee.

Senator CLARK. I would be glad to have you do both, Doctor, if you care to.

Dr. WOODWARD. It may lead to some discussion and it may lead to helpful criticism by speakers who may follow me.

I would rewrite this subsection (b) of section 201 so as to read as follows:

(b) The term "drug", for the purpose of this act, includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them, and all substances and preparations (except food) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or of the disorders of pregnancy, in man and other animals, or for use internally in the promotion of health.

Subsection (c): I would then have:

(c) The term "therapeutic appliance" includes all devices (but not food, drugs, or cosmetics) intended to affect the structure or any function of the human body or the body of any animal, in connection with the diagnosis, cure, mitigation, treatment, or prevention of disease or the diagnosis and treatment of pregnancy.

Then I would insert a chapter dealing with the "adulteration", so-called, and the misbranding of therapeutic appliances, placing the therapeutic appliances in a chapter by themselves, on a par with the chapters on foods, drugs, and cosmetics. It might be as well to point out here the suggested definitions of misbranding and adulteration, if you can call it so.

I would put on page 20, after line 20, the following new chapter:

SEC. 501. A therapeutic appliance shall be deemed to be adulterated within the meaning of this act—if it has not (1) the structural and mechanical properties and the power to produce the kind and quantity of energy claimed for it by the seller, whether electricity, light and light waves, radiant energy, heat, or any other form of energy, or (2) the diagnostic, curative, palliative, preventive, and invigorating properties that it is represented by the seller as having.

SEC. 502. A therapeutic appliance shall be deemed to be misbranded within the meaning of this act if it is not labeled so as to show (1) the name and address of the seller; (2) its structural and mechanical properties, insofar as they relate to the diagnosis, cure, mitigation, and prevention of disease and the increase of bodily vigor; and (3) such claims as the seller makes for it as to the generation of energy, whether electricity, light and light waves, radiant energy, heat, and any other form of energy, (4) together with such cautionary information as may be necessary in the interest of safety; but the Secretary, when such marking is in his judgment impracticable, may waive or modify this requirement to the extent of its impracticability.

I submit that for the consideration of the committee. It was drafted hurriedly. Of course, if the changes are made other portions of the act would have to be modified accordingly.

I should caution with respect to the use of the word "disease" in subsection (b) of section 201 and elsewhere in the act, because it is a rather uncertain word. It may be held to include one thing or another. It ought to be defined in some way. I recall a case in which it was proven to the satisfaction of the presiding justice that child-bed fever was not a disease peculiar to women. Everything hinged on the meaning of the word "disease" in an insurance policy. You may find a similar subtle interpretation of this law unless it is forestalled by definition here.

I should say that the definitions of the terms "medical profession" and "medical opinion", on page 3, lines 17 to 23, subsection (k) of section 201, are simply impossible. I realize the difficulty of defining the term "medical opinion", but I do not believe that it is solved in that section. That section, as I see it, would lead to many standards in many parts of the country, and a standard that would vary from time to time. The best I can suggest as a substitute is as follows:

The term "medical opinion" means the opinion of representative practitioners of the healing art, who have special scientific and professional knowledge of such facts, hypotheses, theories, and principles as those at issue in the case, based on special study, training, and experience, such opinions to be proven by their publications issued within a reasonable time before controversy arose and/or by their sworn testimony, subject to cross-examination.

I recognize, of course, the fact that the introduction of books in evidence is not usual. So far as I know, there are only two States where, by statutes, they may be introduced in evidence. But if you can arrange for the introduction of standard books and publications that were issued before the controvery arose, you will help to standardize the situation throughout the country and you will get an opinion that is not biased by any issue at hand.

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Senator CLARK. It might also have a tendency to stop scientific progress, might it not?

Dr. WOODWARD. No; I do not think it would. I do not think you can stop doctors from writing their books or magazine articles. That is part of the profession.

Now we come to the provision relating to prescriptions of physicians. It seems to me that it is really necessary that there be some exemption of physicians' prescriptions from the labeling requirements of the act as it now stands. In most States those labeling requirements will not apply to physicians' prescriptions. In the District of Columbia, of course, it will, and you may find a similar situation in towns and cities that are on State lines. I can see no harm that will result from such an exemption, and to meet that I suggest that on page 20, after line 14, there be inserted a new subsection to be designated subsection (m) of section 402, reading as follows:

Notwithstanding anything in this act, a drug prescribed in writing by a physician for the use of a patient under his professional care and compounded and/or dispensed by a registered pharmacist or under the supervision of such a pharmacist need bear no label other than (1) the registered name and address of the pharmacy where compounded or of the proprietor thereof, (2) the name of the prescribing physician, and his registration number under the Federal Narcotic Law, if so required by law, (3) the date when compounded, and (4) such instructions for use as may have been given by the prescribing physician.

That, I think, will solve the question without exposing anybody to injury.

Senator COPELAND. You are going to leave that language here, are you not?

Dr. WOODWARD. I shall be very glad to.

Senator COPELAND. Does that cover the point raised by the District of Columbia Society? I suppose it does.

Dr. WOODWARD. I have not been in touch with that society since I came here.

Senator COPELAND. As I remember the letter that the chairman handed me this morning, it does relate to the same subject.

Dr. WOODWARD. I have not seen it, I do not know, but I think it would cover it.

There should be a certain amount of caution throughout the act with respect to foods and with respect, particularly, to confectionery that contain drugs. I think there should be some provision in the act somewhere whereby medicated foods should be distinguished by some label. I will not go so far as to say in every case they ought to be sold as drugs, but the public ought to be protected against the medication of foods and confectionery.

Senator CLARK. What do you mean by "medication of foods"? Does that mean such things as gluten bread, for instance?

Dr. WOODWARD. I should hardly think so, but where you put a laxative in food, particularly in the case of confectionery—confectionery, you realize, is food under this law—where you add laxatives to confectioneries they are dangerous. You would be surprised the number of children dying of strychnine poisoning, getting hold of confections of all kinds, even chocolate-covered pills containing strychnine. We have one member of our organization that has been endeavoring to get us to sponsor legislation throughout the United States that would forbid the use of strychnine in these popular laxative remedies.

Senator CLARK. You would not include such things as gluten bread, composed entirely of natural ingredients, but prescribed by doctors occasionally for particular ailments?

Dr. WOODWARD. Not at all. I would include the things with drugs, within the meaning of this act, that go into the food or candy.

I come now to a matter that is in another part of the act, but it is a matter that I have studied for a long while, that is the promulgation of regulations. So far as I can discover, the provisions of this bill regarding the promulgation of regulations are far more rational, far superior to any provisions that have ever been incorporated in any law that is now in force, for the protection of the persons who must live under those regulations. There is only one criticism that I would offer, and that is this:

On page 28, lines 20 and 21, appear the words "which date shall not be", that is the effective date of the regulation, "prior to 90 days after its promulgation." But the bill makes no provision as to how the regulations shall be promulgated, makes no provision as to how they shall be published, or how the public shall have access to them.

I suggest that promulgation be by publication in three or more consecutive issues of any established organ that the authorities may see fit to use.

Senator CLARK. The Journal of the American Medical Association?

Dr. WOODWARD. We would be glad to undertake such publication, but I would prefer to see the Department of Agriculture establish its own official organ, similar to the Treasury Decisions and the Internal Revenue Bulletin, published by the Treasury Department. That is where regulations promulgated by the Secretary should be published.

My idea is that on page 29, line 2, after the word "departments", there should be added:

Promulgation shall be by publication in three or more consecutive issues of [insert name of proper publication], and not less than 90 days shall intervene between the last day of publication and the day on which the regulation promulgated becomes effective. The Secretary shall report to the Congress annually in the month of January the full text of all regulations which became effective during the calendar year immediately preceding, arranged chronologically according to the dates when they became effective and each annotated so as to show the changes, if any, made in it subsequent to its promulgation, and its status at the close of the year. The Secretary's report, duly authenticated and properly indexed, shall be published as an official document and shall be receivable in evidence in all courts of the United States to prove the regulations in force.

There you have a method of notifying everyone of what has been done and what the law is at any time. I submit that for the consideration of the committee.

The provision that the regulations may be repealed only in the same manner in which they have been promulgated seems to me to be rather inadvisable and liable to meet with difficulty. It ought to be possible to repeal a regulation rather expeditiously if experience shows that it is not effective, and yet, under this bill, you must wait 30 days for a hearing and 90 days after promulgation, before repeal can become effective.

Senator COPELAND. Where is that found?

Dr. WOODWARD. You mean about the repeal?

Senator COPELAND. Yes.

Dr. WOODWARD. That appears on page 28, lines 21 and 23, beginning at line 18:

> The regulation so promulgated shall become effective on a date fixed by the Secretary, which date shall not be prior to 90 days after its promulgation, and may be amended or repealed in the same manner as is provided for its adoption.

Reference has been made as to the possible, I might say probable, unconstitutionality, of some other provisions in the act with respect to factory inspection.

Senator COPELAND. We have had a good deal of testimony on that subject.

Dr. WOODWARD. I have heard it. What I shall have to say has reference to what appears beginning on page 32, at the bottom of the page, line 24. That is section 707 (a). It looks to me as if an effort were being made to protect the constitutionality of those provisions of the law by writing in "protect public health and welfare", so as to impress the court, if you will, as to the reason for the regulation. I do not believe that adds anything to the constitutionality of it. If I were to suggest a change that might go farther and protect the constitutionality, I would add to the end of that section, in line 13, after the word "stored" the following: To the extent that they or any of them are used for the manufacture, storage, display, or transportation of foods, drugs, and cosmetics for interstate commerce. This would limit the right to inspect to the extent that they, or any of them, referring to factories, warehouses, establishments, or vehicles and equipment, are used for the manufacture, storage, display, or transportation of food, drugs, and cosmetics in interstate commerce. I have no doubt of the constitutionality of a law that limits the Federal right of inspection to interstate commerce, but in the broad way in which that right is provided for in the draft, I should question it.

Senator COPELAND. I think we are all agreed on that.

Dr. WOODWARD. I should like very much to see some definite provision made here for insuring the cooperation even more effectively than at present of State authorities. I believe that a great deal could be accomplished in that way. I remember referring at a previous hearing to a provision in the law establishing the Bureau of Narcotics, that makes it mandatory on the Secretary of the Treasury to cooperate with State authorities not only in the enforcement of their laws but in the drafting of such laws as may be necessary. I am quite sure that that provision is working very satisfactorily and to the advantage both of the Federal Government and of the States.

I know, of course, that the Department of Agriculture does cooperate with State organizations, but the position of the representative of the Department of Agriculture under the proposed amendment to this bill would be different. If he goes into a State to cooperate in matters of this kind and there is any objection made to his presence, then he could say, "I am sorry, but it is mandatory under the act of Congress, and I am merely doing what I have to do." I am not here to speak for the Commissioner of Narcotics, but in a conversation with him a few days ago he assured me there was a very different relation since that provision had been made. Under such a system the Federal department might learn a good deal at the factory and food plants in a State through local authorities.

If we turn now to page 14, lines 10 to 18, I should say that in the present form that language was not safe language in a food, drug, and cosmetic bill. It provides that after establishing a fixed standard, a pharmacopoeial or formulary standard—

> No drug shall be deemed to be adulterated under this paragraph because it differs from the standards of strength, quality, or purity therefor set forth in an official compendium if its label bears in juxtaposition with the name of the drug, a statement indicating wherein its strength, quality, and purity as determined by tests or methods of assay applicable under this paragraph, differ from the standards therefor put forth in such compendium.

If there is to be a standard for pharmacopoeial or formulary drugs we should have a standard, and I should suggest that if there is to be any variation allowed, the same rule should be applied there that is applied to imitation foods, and that the law should require that before the name of the drug there appear in letters equal in size to those used in the name of the drug, the word either "attenuated" if the drug has been weakened, "fortified" if it has been strengthened, or "modified" if it has been otherwise changed.

Senator COPELAND. Doctor, if you will find some plan to cover these variations Congress will strike a medal for you.

Dr. WOODWARD. If you apply them to the same principle that you apply to imitation foods, your difficulty will be solved, because if you have an attenuated tincture of opium U. S. P., or fortified tincture of opium U. S. P., or a modified tincture of opium camphorated U. S. P., you give the purchaser notice that it has been either attenuated or fortified or otherwise changed. The purchaser has not a fair show now even if he is a doctor.

Senator COPELAND. Have you made that clear in the notes that you are going to leave with us?

Dr. WOODWARD. I will be glad to leave a note here that has reference to the imitation of foods, because the same principle should be applied here to fortified, attenuated, or modified drugs. On page 6, beginning with line 7, section 302 (c), there is some wording with respect to the labeling of imitation foods. I think the subsection is rather badly drafted. It reads:

> If it is an imitation of another food, and its label fails to bear, in type of uniform size and prominence, the word "imitation", then, immediately thereafter, the name of the food imitated.

It says, "Uniform size and prominence", but it does not say uniform with what. I would suggest that that be rewritten, as follows:

> If it is an imitation of another food and its label fails to bear, immediately before the name of the food imitated, the word "imitation" in letters equal in size and prominence to the letters in the name of the imitated food.

It is exactly the same principle but a restatement that I think clarifies it.

Throughout the bill it seems to me there should be some provision for the printing of labels in the English language. Now it may be presumed, and courts may have ruled—I have not looked the matter up—that where a label is required to appear on a food, under a Federal or State statute, it must be printed in the English language.

Senator COPELAND. That is quite a confession for a doctor to make, where the profession from time immemorial used terms that the laity could not understand.

Dr. WOODWARD. Yes; and the penmanship, too.

As an illustration of what I mean, if you will turn to page 6, lines 15 to 22, section 302 (e), we have the provision that a food shall be deemed to be misbranded, "if in package form it fails to bear a label containing: (1) The name and place of business of the manufacturer, packer, seller, or distributor," and so on. I would insert there, "fails to bear a label containing, in the English language and in terms of English measure," and adding at the end of the paragraph a provision that "a literal translation of the matter on the label into any language or languages other than English and into the terms of any system or systems of measure other than the English system also may appear on the label, in addition to the required statement in English." That, I think, would tend to clarify the situation.

We have heard a great deal about the labeling of drugs, proprietary medicines and others, to show what they contain. I want to say that so far as the American Medical Association is concerned it stands absolutely for the provisions of the present bill, that a proprietary medicine taken and used for self-medication ought to indicate to the patient what he is taking. It has already been pointed out here that the manufacturer of a proprietary remedy can change the ingredients, both quantitatively and qualitatively, at his pleasure, and a man does not know when he takes a remedy what is in it. The one who takes the same remedy from day to day does not know that he is getting the same dosage.

So I want to endorse the provisions that appear on page 16, lines 7 to 19, section 402, subsection (d).

If there is any objection to the right of the Secretary to promulgate regulations adding to the list of drugs that are named in the statute, some limitation might be placed there to indicate that he could add drugs only when their habit-forming properties were established by substantial, reliable medical opinion. But it does seem to me that with the provisions of this bill, whereby the Secretary can have trade groups, trade committees, in addition to his committee on food standards, and his committee on public health, we would be fully able to trust the Secretary's judgment with respect to the matter.

Senator COPELAND. Would this language cover what you have in mind?

Dr. WOODWARD. It covers it very well.

Senator COPELAND. I was going to suggest a change, beginning in the middle of line 12, to have it read, "or any narcotic or hypnotic substance chemically derived therefrom, unless that substance is clearly not habit-forming", and then omit the language down to line 16, and continue, "and its label fails to bear" and so on.

Dr. WOODWARD. There may be other drugs that come along, and I should prefer that the Secretary be authorized to add those to the list.

And I should like to see inserted in line 16, before the word "name" the word "popular", and after the word "name" "if any,", so it will read, "and if label fails to bear the popular name, if any." I remember when the act of 1906 was passed that the high-sounding difficult chemical names were used, or attempted to be used, in order to evade the provisions of the statute. If we require the popular name I think we would avoid the trouble to a great extent.

At this point I want to call attention to the desirability of regulating, further than is done by this section, the manufacture and distribution

of cannabis, otherwise known as "marihuana." It seems to be a great menace to the country because it is used by young people, particularly, and by many others, for smoking purposes, to produce stimulating and other pleasurable sensations. The drug is one that has been and is grown in this country very readily. It is one that can hardly be reached under the taxing power, and yet it is a menace. You will be told, I think, possibly by manufacturing chemists, that they never heard of a cannabis habit. I think, as a matter of fact, that cannabis habit has been extremely rare up to recent years.

Senator CLARK. Where is this raised, Doctor?

Dr. WOODWARD. You can raise it in your back yard. You can raise it in Missouri. The Legislature of Missouri has passed the marihuana act within the past 10 days. Many States have legislation against it.

Senator CLERK. Is it widely produced in this country, Doctor?

Dr. WOODWARD. Not for commercial purposes. The only commercial use is for the manufacture of hemp, hemp rope, and things of that sort, birdseed, and certain drying oils. The drug seems to have been introduced here from Mexico, where the Mexicans use it very largely for smoking, and they use it in the United States at the present time.

Senator COPELAND. Do you propose to prohibit its use?

Dr. WOODWARD. There is a bill pending in Congress now before the Committee on Interstate Commerce that might very well be modified to go in at this point. I do not believe the Commissioner of Narcotics would have a right to feel that he had been passed over. This is S. 1615 [reading]:

A bill to prohibit the shipment and transportation in interstate or foreign commerce of cannabis and its derivatives and compounds.

That the shipment or transportation of cannabis in any manner, or by any means whatsoever, in interstate or foreign commerce is hereby prohibited, except when shipments are transported for medical or legitimate purposes by the producer or manufacturer thereof or dealers therein to licensed physicians, dentists, surgeons, pharmacists, druggists, and veterinarians, under such rules and regulations as shall be prescribed by the Commissioner of Narcotics.

Senator COPELAND. Should that not go to the Narcotic Commissioner?

Dr. WOODWARD. In view of the fact that it is passed under the interstate commerce authority, and not under the taxing authority, in view of the wide-spread force the Department of Agriculture has for the control of these drugs, I think it could be much more effectively done that way than by the Commissioner of Narcotics.

Senator COPELAND. Who introduced that bill?

Dr. WOODWARD. Senator Hatch. I think that could fit admirably in there.

Senator COPELAND. What number is it?

Dr. WOODWARD. 1615.

Now we come to another subject concerning which we have heard a great deal; that is, the matter of the proof of adulteration. If you turn to page 15, lines 13 to 15, in section 402 (a), we find that the labeling of a drug is deemed to be misbranded—

if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion.

It has already been suggested that the word "reliable" be introduced before the word "medical", making it read, "by demonstrable scientific fact or substantial reliable medical opinion."

I would go somewhat further and I would insert there, "by the preponderance of", so as to make it read:

by the preponderance of demonstrable scientific fact and/or substantial, reliable medical opinion, but falseness or misleading character may be established also by any other competent evidence.

It is easy to establish a thing by scientific facts if you select your facts. When the other side have selected their facts it is a question of the preponderance of evidence, or the preponderance of facts.

Senator CLARK. That is, of course, the ordinary rules of evidence in every court in the United States, isn't it Doctor?

Dr. WOODWARD. I am following the statutory provision.

Senator CLARK. Doctor, it is the ordinary rule of evidence in every court that I know of in the United States. Any issue in a civil suit must be proven by the preponderance of evidence.

Dr. WOODWARD. Yes. You are changing it here by simply saying, "if there are substantial facts"; that is all there is to it.

Page 16, line 24, I believe that the provision for the inclusion of the "names and quantity or proportion" of the ingredients of drugs should be retained. It is proposed here to strike them out. I talked that over with my associates in the Chicago office; and we are all agreed that that should, by all means, be retained. I cannot see how it can possibly do any harm.

On page 23, line 24—section 601 (a)——

Senator COPELAND. Mr. Benson presented some suggestion about this language.

Dr. WOODWARD. All I have to suggest there is the elimination of the phrase:

in any particular relevant to the purposes of this Act regarding such food, drug, or cosmetic.

I cannot see any reason why any manufacturer or distributor of food should request or seek authority to make any false or misleading statements with respect to any feature of his product, and I cannot see how anyone can object to the elimination of those words.

I shall be glad to submit whatever else I have to say there in memorandum form for the committee.

Senator CLARK. We would be very glad to have you do it, Doctor.

Dr. WOODWARD. I suggest that there are certain weasel words, if you will, in the act, as where you use the word "insanitary" to indicate the contamination of a food if it has been exposed to "insanitary" conditions which may render it dangerous to health. I cannot see that the word "insanitary" adds anything to the meaning of the act, because if a food, drug, or cosmetic has been exposed to conditions that may render it dangerous to health, I think that ought to be enough.

Senator COPELAND. You would have to prove it otherwise.

Dr. WOODWARD. You might have to prove not only the contamination but to prove also that the contamination was due to "insanitary" conditions. It would be a question as to what "insanitary" conditions were.

I think there ought to be some reconciliation with respect to the use of the words "danger", or "dangerous" and "injury." Some reference has been made this morning to the use of the word "injury." If you have to prove injury, it may be difficult to do it. You may be able to prove that a thing is dangerous.

Another word that I think requires some explanation appears with regard to the acceptance by the Secretary of the cooperation of trade groups. On page 31, lines 9 to 14, section 704, it is provided:

To aid in securing compliance with the requirements of this act, the Secretary is further authorized to accept plans for such self-regulation of advertising or trade practices as can tend to effectuate the purposes of this act——

Senator COPELAND. What page is that?

Dr. WOODWARD. Page 31, lines 9 to 14. [Continuing:]

as tend to effectuate the purpose of this act, when presented by associations or groups representative of their industries.

I have in mind the meaning of the word "accept" in that place. I can get out of it no clear meaning as to the significance of the acceptance.

I will say here with respect to the proposed placing of representatives of trades on the committee on health that I can see no possible need for it, for putting interested persons on it. I can see no possible need for the establishment of panels, because under this section of the law the Secretary can get or he will get all of the expert advice that he needs, and I should think that the committee on health and committee on food standards ought to be absolutely unbiased persons.

Finally, I hope that the entire matter of advertising will remain with the Department of Agriculture. I can see no reason why it should not be. They have the field force; they have the facts, and if the matter remains with the Department of Agriculture, the small man in the field, in remote parts of the country, will be able to get a fair show in his day in court.

Senator CLARK. Of course, when you say, "remain with the Department of Agriculture", you do not need to have it transferred to the Department of Agriculture.

Dr. WOODWARD. No. As I understand it the Federal Trade Commission at present has jurisdiction with respect only to cases in which there is competition between commercial interests, if you will.

Senator CLARK. That is perfectly so. Under the present law the Federal Trade Commission is the only governmental agency that has any authority, or that has had any authority whatever up to date to deal with advertising. In other words, my understanding is that the Department of Agriculture has been absolutely helpless in the matter up to date.

Dr. WOODWARD. So it has, and so has the Federal Trade Commission.

Senator CLARK. I am not arguing with you as to whether that agency ought to be split, but certainly when you say remain "in the Department of Agriculture" you are not quite accurately stating the present situation. In other words, from the contentions you are now making, a new agency is being created. It is not the question of it remaining either with the Federal Trade Commission or with the Department of Agriculture, because at present no governmental agency has authority in that class of cases.

Dr. WOODWARD. I have no word to say against the Federal Trade Commission, because I think it did a magnificent piece of work in suppressing fraudulent medicines, and advertising, and things of that kind, up to the point where its hands have been tied by the decisions of courts.

Senator CLARK. Their authority had been limited to the matter of fair trade practices.

Dr. WOODWARD. That was a matter of discretion.

Senator CLARK. At the present time, as I understand it, the Department of Agriculture has absolutely no authority with regard to advertising matters.

Dr. WOODWARD. Absolutely. We should like to see them have that authority, so that manufacturers and dealers everywhere throughout the country, instead of being compelled to come to Washington for a hearing or presentation of some possibly picayune case before the Federal Trade Commission, taking up their money and the time of the Federal Trade Commission with something that can very well be settled locally.

Then as to the cease-and-desist orders, the Secretary is just as able to, has just as much right to issue cease-and-desist orders, as has the Federal Trade Commission, because there is an express provision that the Secretary need not prosecute minor cases, and if he feels that a case is a minor case, an agreement whereby a man will cease and desist is just as much within his authority as is a cease-and-desist order in the authority of the Federal Trade Commission.

Senator COPELAND. Doctor, have you spoken for the American Medical Association in what you have said?

Dr. WOODWARD. I have spoken for the American Medical Association. I am glad you spoke of that. The American Medical Association formulated certain principles that in the judgment of the association, as represented by its council on pharmacy and chemistry, and its committee on foods, to govern the enactment of legislation.

Senator CLARK. Will you insert that in the record?

Dr. WOODWARD. I will be glad to insert it in the record.

NEW FOOD AND DRUGS LEGISLATION

The Council on Pharmacy and Chemistry and the Committee on Foods of the American Medical Association have adopted respective statements concerning the revision of the Food and Drugs Act. These statements, in turn, have been endorsed by the board of trustees; publication has been authorized by the council, the committee, and the board.

Austin A. Hayden, secretary of the board of trustees.
Paul Nicholas Leech, secretary of the council on pharmacy and chemistry.
Raymond Hertwig, secretary of the committee on foods.

REPORT OF THE COUNCIL ON PHARMACY AND CHEMISTRY ON REVISION OF THE FOOD AND DRUGS ACT IN SPECIAL REFERENCE TO DRUGS

In the 30 years since the Federal Food and Drugs Act became law there have been notable developments in scientific, technologic, and economic fields and many changes in methods of manufacture, distribution, and sale of drugs and drug products. Experience in the administration of the act has brought to light various ways in which the law is inadequate to meet modern conditions. To the end that public health and safety shall be better safeguarded in the matter of the manufacture, distribution, and sale of drugs and related products it is important that the provisions of the present law be revised and its scope enlarged.

The council on pharmacy and chemistry of the American Medical Association therefore deems it desirable that the law be amended (or a new law be made):

1. To include provisions for so regulating all forms of drug advertising that it shall be truthful in statement and not deceptive by implication; the terms "advertising" to include all ways and means of bringing articles to the attention of the public for commercial purposes.
2. To provide that responsibility for advertising rest with the individual or firm issuing it unless such individual or firm produces a guaranty as to the truthfulness of the advertising claims, and the guarantor is amenable to the terms of the act; in which case the guarantor shall be responsible.
3. To provide that the active ingredients and the amounts or proportions thereof in all mixed drug products not listed in official compendiums (U. S. P. and N. F.) be disclosed on the labels of such products and in the advertising of them.
4. To prohibit the sale of drugs and drug preparations under names recognized in official compendiums (U. S. P. and N. F.), unless such drugs and drug preparations meet the standards and specifications laid down in such compendiums.
5. To require suitable declaration on labels and in advertising of any and all habit-forming drugs, whether sold singly or in mixtures, together with explicit warning that such may be habit-forming; provided that such declaration be not required in the case of drugs or mixtures of drugs dispensed on prescription, and which are to be used according to directions of a physician.
6. To provide for official announcement by the Government of such drugs as may now be held, or in the future be determined, to be habit-forming.
7. To prohibit the mention of disease names on the label of drugs or drug preparations, or in advertising thereof, unless such drug or drug preparation is a cure for the disease named; or unless such drug or drug preparation is a palliative and the nature of the palliative action is stated.
8. To extend the provisions of the law to include cosmetics and the advertising thereof, the term "cosmetics" to include all substances and preparations intended for cleansing, altering the appearance, or promoting the attractiveness of the person, unmedicated soaps excepted.
9. To extend the scope of the term "drug" to include devices, substances, and preparations intended for the treatment of disease and all devices and all substances and preparations, other than food, intended to affect the structure of any function of the body; this provision to be for the purposes of the act and not to regulate legalized practice of the healing art.
10. To prohibit the addition of drugs to foods and confections intended or offered for general human consumption, but not to prohibit such addition to, or other modification of, foods and confections intended or offered to meet special nutritional requirements or dietary needs, provided the label and advertising of products so treated plainly declare the character and purpose of such modifications.
11. To require that testimonials and opinions used in advertising of drugs and drug preparations be accompanied by the name and address of the writers thereof, and to consider such testimonials and opinions as advertising claims of the advertiser.
12. To provide by permit or license or other means for Government control over the sale and distribution of such drugs and therapeutic agents as cannot be adequately controlled by gross inspection or chemical examination of the finished product, except that this shall not apply to the provisions of the Serums and Vaccines Act of 1902 and amendment thereto.
13. To require each importer, manufacturer, jobber, and retailer engaged in interstate commerce in drugs and therapeutic agents to register with the Government his name, place of business, and the character of the business in which he is engaged or proposes to engage; such registration to be granted without cost to the applicant and accepted only on evidence showing adequacy of plant, equipment, and personnel for the business proposed.
14. To provide for cooperation between Federal and State governments in the enforcement of food and drug laws in their respective jurisdictions on a plan similar to that provided in "An act to create in the Treasury Department a Bureau of Narcotics, and for other purposes", approved June 14, 1930.
15. To require labels on drugs and drug preparations to bear the name and address of the manufacturer, seller, or distributor; and to bear a statement of the net weight or volume of contents.
16. To provide for more adequate penalties, which will be commensurate with the seriousness of violations.

REPORT OF THE COMMITTEE ON FOODS ON REVISION OF THE FOOD AND DRUGS ACT WITH SPECIAL REFERENCE TO FOODS

The committee on foods of the American Medical Association, solely from the standpoint of greater consumer protection with respect to nutrition and health, deems it desirable that the present Food and Drugs Act be amended (or a new law made):

1. To include provisions for so regulating all forms of food advertising that it shall be truthful in statement and by implication.
2. To ban the use of names of diseases on the labels and in lay advertising of common foods but not to exclude names of nutritional disorders arising from inadequacy of the diet in nutritional essentials or of disease names from the labels and advertising for special purpose foods which are useful in the diet during the course of such diseases.
3. To ban the use of testimonials of a health, medicinal, or therapeutic character, or with such implication, in food advertising by persons unqualified to express a scientific authoritative opinion or judgment on the subject of the testimonials.
4. To authorize the fixing of tolerances for any added or natural poison in or on food and consider food as adulterated which bears or contains any poisonous or deleterious substance, in excess of the tolerances, which may render it dangerous to health irrespective of whether that constituent is added by man or exists their naturally.
5. To prevent the use of nonfood material such as resinous glaze or shellac to cover confectionery.
6. To ban the embedding of metallic trinkets in confectionery, which may result in their aspiration and lodgment in the windpipe.
7. To prohibit the use of any artificial colors in food other than those certified by the Department of Agriculture, thereby preventing the use of toxic colors.
8. To class as adulterated food prepared under insanitary conditions whereby it may have become contaminated with filth.
9. To include a provision against packing food in containers or wrappings which may injuriously contaminate the food.
10. To authorize the establishment of legal definitions and standards for foods.
11. To consider as adulterated a food purporting to be one for which a definition and standard has been prescribed if it fails to conform to such definition and standard, and the label does not conspicuously indicate deviations from the definition and standard.
12. To require that the label of foods shall bear their common or usual names if there are any, and in conjunction with the names declare the common or usual name of each ingredient article used in the manufacture of the food in the order of decreasing predominance by weight, exceptions being made for spices or other condiments, colors, flavors, and leavening agents.
13. To require that fanciful trade names for food be accompanied by statements identifying the ingredient articles used in the manufacture of the food in the order of decreasing predominance by weight, exceptions being made for spices or other condiments, colors, flavors, and leavening agents.
14. To require that informative statements required on labels be conspicuously placed thereon in simple common terms so as to be readily observed at the time and under the conditions of purchase.
15. To require that the labels of special-purpose foods with usefulness restricted to specific purposes such as inclusion in diets for obesity or special morbid conditions, shall prominently display in bold type the designation "Special-purpose food", a statement listing all ingredients in the order of decreasing predominance by weight, and the special purpose of the product. These statements, so far as is practical, should be in close proximity to the trade name. In addition, as much of the following information should be given as is significant to permit the intelligent use of the particular product by the consumer: Specific properties, vitamin and mineral content, the calories per gram or ounce, and the grams each of carbohydrate, protein, and fat per portion.
16. To require that special values or properties of food, if given, be stated in specific, recognized technical terms or units.
17. To require that labels bear the name and place of business of the manufacturer, seller, or distributor of foods.
18. To authorize Federal enforcement officials to enter on and inspect premises of those manufacturing, storing, and dealing in foods in order to protect adequately the health of the public.

19. To authorize certain officials to effect seizure of food before the filing of a libel in courts, and to hold same pending court action where the evidence before the enforcement officials is such as to indicate that the food is imminently dangerous to health.
20. To provide adequate penalties for those violations of the law affecting the nutrition and health of the consumer—(Journal of American Medical Association, 104–125, Jan. 12, 1935.)

Senator CLARK. Dr. McCormack.

STATEMENT OF DR. A. T. McCORMACK, STATE HEALTH COMMISSIONER OF KENTUCKY

Dr. MCCORMACK. My name is Dr. A. T. McCormack. I am the State health commissioner of Kentucky, chairman of the Committee on Federal Relations of the Conference of State Health Authorities, and delegated to represent the State health authorities in the discussion of this bill, after having full discussion of it at our annual meeting last year and having had repeated round-robins correspondence in regard to the modifications of it that have occurred since. I appreciate the opportunity of supporting legislation prepared and sponsored by one of the most distinguished physicians and public-health authorities of the world, Dr. Copeland.

Of course we are tremendously interested in this legislation. It is one of the most important forward steps that are needed.

We were engaged actively in the passage of the original law. We have seen gradually developed many practices that have succeeded in evading the purposes of that law that need to be corrected and can only be corrected by the passage of new law. I was particularly interested this morning in hearing my old friend Judge Davis that for 20 years the Federal Trade Commission had jurisdiction and ample control over advertising and could control the entire matter with very slight modifications in their law. They have accomplished a good deal in the matter of unfair trade practices in the last 20 years, but if what they have done in the past 20 years is any sort of evidence of what they will do in the next 20 years I would say that we would be in the same fix in regard to very much of the misleading advertising announcements at the end of 20 years that we are in now.

Advertising is really an extension of the label. It is what the printed material around the carton really means, it is the little booklet or the almanac that advertises the product, or the newspaper or radio announcements. That is merely an extension of the label.

Senator CLARK. I agree with you thoroughly on that, except we do not make any restrictions on the Federal Trade Commission, because they have been the only agency in the last 20 years that had any authority.

Dr. MCCORMACK. I do not mean to reflect on them. I just mean to say that that agency has already done what it can, with its limitations.

Now we have for 29 years come in contact with the Bureau of Chemistry that has had the enforcement of this law. We have found one difficulty that is perpetuated in this bill.

I think it ought to be called to the attention of the committee, although I doubt if it could be corrected. The great mistakes that have been made in the administration of the Food and Drug Act have not been made by the Bureau of Chemistry, but have been made by

the over-ruling of the rulings of the Bureau of Chemistry by the secretaries on political matters. Take for instance the corn-sugar hearing, President Taft's overruling of the Bureau in regard to "what is whisky" probably caused the passage of the eighteenth amendment and cost an enormous amount of expenditure in the United States and has possibly made the whole enforcement of any law in regard to the control of liquor impossible in the future, because there is no standard for whisky.

It can be made out of anything—anywhere, any time, by anybody—and you cannot confine it to its legitimate channels by law or by any means. We all are seeing the evils of that decision even to this day. If the decisions could be confined to those who are qualified to render them, as Dr. Wiley was, or as the present Chief of that Bureau, political pressure would have no effect and the public would benefit from scientific as distinguished from political decisions.

In the States we are coming in contact with these scientific bureaus all the time. I am from a State that I think is peculiarly individualistic. We are suspicious of foreigners whenever they come to us. Most of them have brought us gold bricks and naturally we take it for granted that if they come down there they are coming for that purpose. But we have found that the scientific bureaus have brought to our people knowledge, safety, and protection. The opposition to them, that we hear so much about, has not come from the people they have served, but has come from the interests that have been deterred from preying on the people. I think that distinction needs to be kept in all our minds in this whole line of procedure.

It is very important to remember, and I am sure you have kept in mind that the deleterious effects of many advertised or disseminated remedies are not merely their harmfulness or their dangerous or poisonous effects but the delay that they cause in securing the use of the proper thing.

Senator CLARK. A man may personally rely on a remedy which may not be efficacious and delay going to a doctor and getting the proper remedy prescribed.

Dr. MCCORMACK. Absolutely. Take the typical example of a widely distributed product, not a widely advertised but a widely distributed product for the relief of all the diseases to which the female is heir. That was made of a very valuable and expensive remedy. It made everything about the patient a deep yellow after it was used. Therefore, it had a considerable psychological effect. It cost a lot of money and was sold for an enormously high price, and thousands of women have died unnecessarily of cancer that might have been relieved had they not been lulled into confidence by the misuse of such a remedy as this. That sort of thing ought to be preventable by law and people ought to be saved from that kind of thing. There ought not to be permitted the announcement, "take this thing and you are not so likely to have diphtheria", or, "you are not so likely to have consumption." We know it is not true.

Take the repeated advertisements of cures for venereal diseases. It is difficult enough for the scientific specialist to cure most of them, but to announce in the drug stores, or in the labor-union places, or in the streets, or in toilets, as we see them everywhere, remedies "that cure or that are used by the best doctors in the treatment" of

these things that are so difficult to diagnose and to cure, that is a terrible thing that is causing the increased numbers in our asylums and penitentiaries, and causing increases in our death rate unnecessarily.

The health officials of the country, Mr. Chairman, are tremendously interested in the passage of this bill and they approve it in principle.

Many of us look back to the time when your father, Mr. Chairman, and my father were present at a hearing, just as this is, when the thing did not look exactly like it does now. All the noise was being made by the men who had heretofore been openly violating what was then to become the law. Now, instead of fighting the law, attempts are being made by weakening and ingenious amendments to keep it from operating in regard to particular interests, and we hope very much that our representatives—who understand and know that those interested in weakening the law want to do—that they are protecting the interests of the common people in the country. There is no danger of hurting any of these great interests that are selling something honestly.

They talk like they are going to ruin. None of them have been ruined yet by being made honest; none of them have been ruined by being made clean.

We need the great advertising avenues of the country and their wonderful institutions. We need them, we have to have them. They are great educational institutions. But nothing can help them as much as having their advertising clean and having it carry honestly the things we so greatly need.

I have two or three memoranda, Mr. Chairman, that I would like to leave with the committee.

Senator CLARK. They may be made part of the record, Doctor.

(The memoranda follow:)

THE ASSOCIATION OF DAIRY, FOOD, AND DRUG OFFICIALS OF THE UNITED STATES,
Louisville, Ky., March 2, 1935.

To the members of the Association of Dairy, Food, and Drug Officials of the United States:

At a meeting of your executive committee on February 18, 1935, I was instructed as a member of this committee, to prepare for the members of the association, a comparison of S. 5 with S. 1944.

You will remember that the association went on record as follows, at their meeting in Milwaukee in 1933, endorsing S. 1944:

"Whereas in accordance with the report of the special committee appointed to consider the proposed Federal Food and Drugs Act, known as "Senate bill 1944", and

"Whereas it is believed that if this bill is enacted into law it will be of great assistance to the State and municipal officials in the enforcement of food and drug laws, and

"Further, as there is evidenced by the expression of opinion regarding this particular measure of strengthening national control, therefore,

"*Be it resolved*, That this association unanimously endorse this bill and urge its prompt enactment into law.

"*Be it further resolved*, That the President appoint a committee of three to bring this resolution to be attention of the Secretary of Agriculture, Henry C. Wallace, and that this committee also urge officials concerned to render such assistance as possible in bringing about the final enactment of this bill."

This comparison has been hurriedly written for the purpose of giving you this information as soon as possible, since I have definite report that the subcommittee of the Committee on Commerce of the Senate is beginning hearings on S. 5, March 2 through 9, and I feel that you should have this information immediately.

I would advise that my opinion or statement which you would desire to have entered in the record of this hearing, should be sent at once to the chairman of this committee.

Sincerely yours,

SARAH VANCE DUGAN,
Member of the Executive Committee.

A COMPARISON OF S. 1944 AS INTRODUCED BY SENATOR COPELAND IN THE SENATE IN JUNE 1933 AND S. 5 AS INTRODUCED BY SENATOR COPELAND IN JANUARY 1935

The chapters and sections used are those of S. 5 unless otherwise indicated.

Title.—The title of S. 5 is exactly the same as S. 1944, except that the word "drink" has been included with the list of products affected by the bill.

The name of the act is the same except that the word "cosmetic" has been introduced into the name.

CHAPTER II OF S. 5, SECTION 201. DEFINITIONS OF FOOD PRODUCTS

(a) The definition of food is exactly the same as the definition of food under section 2 (a) of S. 1944.

(b) The definition of drug has been changed and the words "for the purpose of this act and not for the regulation of the legalized practice of the healing art" have been inserted as a modification of the word "drug". The Homeopathic Pharmacopoeia of the United States has been also included in the list of publications containing recognized drugs. At the end of section 3 the modifying phrase "of man and other animals" has been deleted from S. 5. This phrase modified the phrase "function of the body" in S. 1944.

(c) The definition of the term "cosmetic" is the same as in S. 1944 except that the following modifying sentence has been eliminated, "except as indicated in (b) (3) of this section, the definitions of food, drug, and cosmetics shall not be construed as mutually exclusive."

(d) The definition of the term "Territory" in S. 5 includes the "District of Columbia", which was not included in the term "Territory" in S. 1944.

(e) In the definition of the term "interstate commerce" in S. 5, commerce "between points within the same State or Territory but through any place outside thereof", has been excluded from the definition of "interstate commerce", and (2) in the definition of "commerce or manufacture within the Territories of the United States" "or the Canal Zone" has been eliminated.

(f), (g) The terms "person" and "Secretary" are identical with S. 1944.

(h) The term "label" has been defined in S. 5 as "principal display or displays of written, printed, or graphic matter." This is slightly different from the definition in S. 1944.

(i), (j) defining "labeling" and "advertisement" are identical with S. 1944.

(k) A new definition defines "medical profession" and "medical opinion."

(l) Defines the term "official compendium." Neither (k) or (l) are included in S. 1944. The definition of "in package form" is not included in S. 5.

CHAPTER III, OF S. 5, SECTION 301. ADULTERATED FOOD

This corresponds to section 3 of S. 1944.

"(a) (1) A food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it dangerous to health." S. 5.	"A food shall be deemed to be adulterated if it is or may be dangerous to health." S. 1944.

The rest of the definition of adulteration (a) and (b) is the same as in S. 1944.

(c) Includes with "confectionery", "ice cream" and exempts "the addition of natural gum and pectin", and provides further "That this paragraph shall not apply to any confectionery or ice cream by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts or to any chewing gum by reason of its containing nonnutritive masticatory substances."

(d) Is the same as in S. 1944.

SECTION 302. MISBRANDED FOOD

(a) Of this section is the same as (b), section 7, of S. 1944.

(b) Of this section is the same as (c) of section 7, of S. 1944.

(c) Is the same as (a), section 7, S. 1944.

(d) Is the same as (a), section 6, S. 1944, except that it has been reworded as follows:

"A food shall be deemed to be misbranded if its labeling is false or misleading in any particular." S. 5.	"A food is deemed to be misbranded if its labeling is in any particular false or by ambiguity or information creates a misleading impression regarding any food." S. 1944.

(e) Is the same as (b) under section 6, S. 1944, except that the provision covering the permission for transportation of unlabeled can goods from the packing plant to the labeling plant is omitted. (This appears in another section of S. 5.)

(f) Is the same as (c) under section 5, S. 1944.

(g) Is similar to (d) under section 7, S. 1944, except that it includes the word "standard" as well as definition and has in addition the following phrase "and if so required by such regulations when such definition and standard permits optional ingredients other than spices, flavors, and coloring, the common names of such optional ingredients as are present in such food."

(h) Is the same as (e), section 7, S. 1944.

(i) Follows paragraph (f), section 7, S. 1944, with the following additional provisions: "If it purports to be or is represented for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by regulations as provided by sections 701 and 703 statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value."

(j) Is now and is not included in S. 1944. Requires special labeling of infant, invalid, and special nutritional foods.

(l) Provides for exemption of food products labeled at a place different from the place they are manufactured, as under section 6, S. 1944.

DEFINITIONS AND STANDARDS FOR FOOD

Section 303 is designed as section 11, S. 1944, except the provisions effecting authority is given to the Secretary only to promulgate, not fix regulations and a proviso is added as follows: "*Provided*, That no standards of quality shall be established for fresh natural foods."

Under S. 1944 the standards were to include "Definitions of identity and standards of quality and fill of container for any food."	S. 5 provides "For any food a definition and standard of identity and a reasonable standard of quality and fill of container."

TOLERANCES FOR POISONOUS INGREDIENTS IN CERTIFICATES OF COAL-TAR COLORS

Section 304 (a) Is the same as section 10 (a) in S. 1944, except that it has been reworded.

(b) Section 10, S. 1944, except as to methods of promulgating regulations.

PERMIT FACTORIES

Section 305 is copied after section 12 (a). The new section provides for issuance of permit "by reason of contamination by micro-organisms" only, it further applies only to foods

In S. 1944, the permit section applied to the manufacturer of drugs or cosmetics as well, "by reason of conditions * * * be injurious to health."

(b), (c) are same as (b) in S. 1944.

CHAPTER IV, SECTION 401. ADULTERATED DRUGS (IS SEC. 4, S. 1944)

(a) "If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof." "Or advertising" is included under labeling."

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(b) This section has been a little reworded and requires that the Secretary cannot prescribe tests or methods of assay for drugs in the official compendium, unless he has notified the appropriate body charged with the revision of such compendium.

S. 1944 permitted the Secretary to prescribe such tests without waiting on the official revision bodies.

The Secretary's name and power to adopt regulations has been taken out of all sections.

A further provision is made covering "Adulterated Drugs" and the recognition of drugs in the United States Pharmacopoeia and the Homeopathic Pharmacopoeia.

(c), (d) are the same as (c), (d), section 4, S. 1944.

Section 402. Misbranded Drugs

(a) is similar to section 4 (a) of S 1944, with the following addition: "Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular such representation is not sustained by demonstrable scientific facts or substantial medical opinion."

(b) Is the same as (b), section 6, S. 1944, as it applies to drugs.

(c) Is the same as (c), section 6, S. 1944, as it applied to drugs.

(d) Is similar to sections 8 (b), S. 1944. The product "marihuana" has been included in the list of forbidden products.

(e) Is similar to (e) under section 8, S. 1944, except that exemption is made from labeling the ingredients of drug products when the formula which has been filed with the Secretary in accordance with regulations prescribed by him.

(f) Provides requirements similar to (d), section 8, S. 1944. Explicit directions for use of drugs and provides for, in addition to the requirements of S. 1944, warning notices against the use of such drugs as may be dangerous to health in pathological conditions, or by children, or by unsafe doses, however, there is a provision that provides that the Secretary may promulgate regulations exempting drugs, from the requirement, providing for complete and explicit directions for use to be on the labeling, for such drugs as are not necessary for the protection of the public health.

(g) Is the same as (f) of section 8, S. 1944, except provisions are made for interpretation of requirements for drugs listed both in the United States Pharmacopoeia and the Homeopathic Pharmacopoeia.

(h) Covering the labeling of drugs liable to deterioration is somewhat different from the similar section of S. 1944, as it requires that the Secretary must inform the revision body of any official compendium before establishing regulations on any drug recognized in such compendium.

(i) Is the same as (h) of section 8, S. 1944.

(j) Is similar to (i) section 8, S. 1944, save that a definite standard is provided for a germicide or a disinfectant and definite methods of providing for the standard testing is provided. It further exempts from the requirement of this section any drugs which are only disseminated to members of the medical or pharmaceutical professions.

(k) Is a new paragraph covering inhibitory antiseptics in the same way germicides are covered in the preceding paragrphs.

(l) Provides for exemption for labeling of drugs that are labeled at establishments other than the original manufacturing place.

Chapter V, Section 501, Adulterated Cosmetics

(a) Has the same effect as (a), section 5, S. 1944.

(b) Is the same as (b) of section 5, S. 1944.

Section 502. Misbranded Cosmetics

(a) Is similar to section 6 (a), S. 1944, as it refers to cosmetics.

(b) Is similar to section 6 (b), S. 1944, as it refers to cosmetics.

(c) Provides for intelligible labeling on cosmetics.

(d) Provides for exempting the labeling of cosmetic products which are labeled in places other than the places they are manufactured.

Tolerances for poisonous ingredients in cosmetics

Section 502 (a): This section is similar to section 10 (a) of S. 1944, except that it covers only poisonous ingredients in cosmetics. Poisonous ingredients in foods are covered in section 304.

Chapter VI, Section 601, False Advertisement

(a), (b) is written in place of section 9 (a), (b), (c) of S. 1944. They are not nearly so comprehensive as S. 1944. The lists of diseases prohibited of mention in advertising is much reduced. The following are the sections of S. 5:

"(a) An advertisement of a food, drug, or cosmetic shall be deemed to be false if it is false or misleading in any particular relevant to the purposes of this Act regarding such food, drug, or cosmetic. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular such representation is not sustained by demonstrable scientific facts or substantial medical opinion.

"(b) It shall be unlawful to advertise for sale in interstate commerce a drug represented to have any therapeutic effect in the treatment of cancer, tuberculosis, venereal diseases, heart and vascular diseases, as well as any other disease which may be added to this list by regulations as provided by sections 701 and 703; except that no advertisement not in violation of paragraph (a) of this section shall be deemed to be false under this paragraph if it is disseminated only to members of the medical and pharmaceutical professions or appears only in the scientific periodicals of these professions, or if it is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs."

Chapter VII, Section 701. General Administrative Provisions—Power to Make Regulations

(a) (b) This is in place of section 23 of S. 1944. The Secretary is empowered to make regulations "except as otherwise provided." As in S. 1944, the Secretary of the Treasury and the Secretary of Agriculture jointly make regulations covering imports and exports.

(c) is the same as (c) in section 23 of S. 1944.

Section 702. Court Review of Resolutions

This is an entirely new section not found in S. 1944, permitting the courts to restrain by injunction the Department of Agriculture from enforcement of a regulation which is unreasonable, arbitrary, or capricious.

Section 703. Public Health and Food Standards Committees

This section is not found in S. 1944 and provides for the formation of two committees which are to act in promulgating regulations with respect to public health and foods. The terms of office of the members shall be for 5 years. The President designates the chairmen of the two committees.

(1) A committee on public health is provided that will consist of five members, designated by the President, with a view to their distinguished scientific attainment and interest in public health and without regard to their political affiliation. No person who is a member of the Department of Agriculture, or who has a financial interest in the manufacture, advertising, or sale of any food, drug, or cosmetic, shall be eligible to serve on the committee on public health.

(2) A committee on food standards is "provided which shall consist of 7 members, 3 of whom shall be selected from the public, 2 from the food producing, processing, manufacturing, and distributing industry, and 2 from the Food and Drug Administration. The members selected from the public and the food industry shall be appointed by the President without regard to political affiliation. The members from the Food and Drug Administration shall be designated by the Secretary. No person who is a member of the Department of Agriculture, or who has a financial interest in the manufacture, advertising, or sale of any food, drug, or cosmetic, shall be eligible to serve as a member from the public on the committee on food standards."

SECTION 704. ADVISORY COMMITTEES FROM INDUSTRIES

This is a new section not found in S. 1944 and provides that the Secretary is authorized to appoint advisory committees from the food industry, the drug industry, the cosmetic industry, disseminators of advertising, and the public. The Secretary is further authorized to accept plans for self-regulation of advertising practices, as they affect the purposes of the act.

SECTION 705. EXAMINATIONS AND INVESTIGATIONS

This is the same as section 15 (a) of S. 1944.

SECTION 706. RECORDS OF INTERSTATE SHIPMENT

This is similar and for the same purpose as section 14 of S. 1944.

SECTION 707. FACTORY INSPECTION

(a) This is for the same purpose and very similar to section 13 (a) of S. 1944.

(b) This is similar in effect to (b) in section 13 of S. 1944.

SECTION 708. PROHIBITED ACTS AND PENALTIES

(a) The 7 prohibited acts defined in this paragraph are the same as the 6 prohibited acts in section 17 (a) of S. 1944.

(b), (c) are the same as similarly identified paragraphs of section 17 of S. 1944.

(d) This section has been rewritten from the one in S. 1944. In the paragraph under S. 5, the liability of advertising is placed directly upon the manufacturer, packer, distributor, or seller who caused the dissemination of the advertisement. The publisher is, however, held responsible for the dissemination of any false advertisement caused by a person residing in a foreign country, unless he can produce a guaranty signed by a person residing in the United States, who will assume full responsibility for the violation.

(e) is rewritten from (e) in section 17 of S. 1944, and is rewritten similarly to (d), just discussed.

(f) is the same as (f) in section 17 of S. 1944.

(g) is not found in S. 1944, and provides that no person shall reveal information concerning any method of process which is entitled to protection in equity as a trade secret. Penalty is provided.

SECTION 709. LIABILITY OF CORPORATIONS AND THEIR OFFICERS

(a), (b) are the same as section 18 (a) (b) of S. 1944.

SECTION 710. INSTITUTION OF CRIMINAL PROCEEDINGS

(a) is the same as section 15 (c) of S. 1944.

(b) is the same as the last sentence of section 15 (c) of S. 1944, except that the following sentence is added to this paragraph: "Nothing in this act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings minor violations of this act whenever he believes that the purposes of the act can best be accomplished by a suitable notice or warning."

SECTION 711. SEIZURE

(a) is similar to section 16 (a) of S. 1944, except the following addition has been made: "And if the court before which the condemnation proceedings are had shall find that there was probable cause for such seizure, it shall issue a certificate of probable cause."

(b) is similar to section 17 (b) of S. 1944, except that cognizance is taken of the additional phrase quoted above in section 711 (a).

(c) is the same as (c) of section 16, S. 1944.

(d), (e), (f) are exactly similar to (d), (e), (f) of section 16 of S. 1944.

(g) provides that the courts are vested with jurisdicion to restrain, by injunction, the institution of more than 3 seizures, after the alleged violation is

one of misbranding only; and further, that the court may libel disposal of an article if more than 3 actions have previously been instituted against such article.

(h) provides for dissolution of any injunction against seizures upon motion of the United States attorney under two different circumstances, as follows:

A certified judgment of condemnation against such article.

A duly certified judgment upon a determination of the issue of misbranding.

SECTION 712. INJUNCTION PROCEEDINGS

(a) This section is rewritten from section 19 (a) of S. 1944, and provides for almost exactly the same proceedings of injunction as provided in section 19 of S. 1944, except that the violations which will permit injunction proceedings are "declared to be a public nuisance."

(b) is the same as (b) of section 19 of S. 1944.

SECTION 713. DUTIES OF UNITED STATES ATTORNEY

Section 713 is the same as section 15 (b) of S. 1944, except the following exemption suits instituted under section 702, paragraph (g), which provides for district courts restraining the Government by injunction, and section 702, are, of course, not instituted in the name of the United States.

SECTION 714. IMPORTS AND EXPORTS

(a) is very similar to section 20 (a) of S. 1944, except that the added prohibition on imported articles is made, "such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported."

(b), (c) are the same as (b), (c) of section 20 of S. 1944.

(d) exempts from the act any food, drug, or cosmetic intended for export and so labeled, so long as it complies with the law of the country to which it is intended for export.

SECTION 715. PUBLICITY

(a) is rewritten from section 21 of S. 1944 but provides that such information "shall not be disseminated except in cases involving imminent danger to health or gross deception of the consumer." This is somewhat different from the provision in S. 1944, "in the interest of public health and the protection of the consumer against fraud"; however, an additional proviso is made as follows: "That nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of this Department."

SECTION 716. SEPARABILITY CLAUSE

Section 716 is the same as section 25 of S. 1944.

SECTION 717. EFFECTIVE DATE AND REPEALS

(a), (b) give 12 months in place of the 6 months as given in section 26 of S. 1944. It further provided, however, that the Secretary is authorized to conduct hearings and promulgate regulations which will become effective on or after the effective date of the act. This section appears to have practically the same effect otherwise as section 26 (a), (b) of S. 1944.

In S. 5, there is no provision made for voluntary inspection service provided in section 22, S. 1944.

There is no section providing for liability for personal injuries, as provided in section 24 of S. 1944.

The provisions under "False advertisement", section 9 of S. 1944, have been greatly changed in S. 5, and are not now nearly so detailed or comprehensive.

Under "Misbranding of drugs", section 8 of S. 1944, paragraph (c), is not covered in any section of S. 5 "If it contains any quantity of ethyl alcohol, ethyl ether, or chloroform, and its label fails to bear a statement, in the manner and form prescribed by regulations of the Secretary, of the quantity or proportion of such substance.

Recommended Amendments to S. 5

Section 305, page 10, line 3: After the word, "food", the words, "drugs, or cosmetics" should be added.

Section 305, page 10, line 4: The words, "by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof, be injurious to health," to be changed to read, "by reason of conditions surrounding the manufacture, processing or packing thereof, be injurious to health."

Section 402, page 14, between lines 14 and 15: A new paragraph should be included as follows: "If it contains any quantity of ethyl alcohol, ethyl ether, or chloroform, and its label fails to bear a statement, in the manner and form prescribed by regulations as provided by section 701 and section 703, of the quantity or proportion of such substance."

The inclusion of this paragraph, would require the relettering of the paragraphs following thereafter in the same section.

Section 703, page 23, line 8: Add, "and the members of the Committee on Public Health shall be appointed by the President from the list submitted jointly by the American Public Health Association, and by the State Health Officers Association."

Section 703, page 23, line 13: The words, "three of whom shall be selected from the public", shall be replaced by the following: "three of whom shall be selected from the list submitted jointly by the Association of Dairy, Food and Drug Officials of the United States, and the Association of Official Agricultural Chemists."

Resolutions Adopted by the Convention of the Kentucky Federation of Women's Clubs, Meeting at Louisville, Ky., May 7–10, 1934

Whereas the Pure Food Act, known as the "Wiley bill", is out of date and the public should therefore be further protected; and

Whereas many foods, drugs and cosmetics are being adulterated, misbranded or falsely advertised; and

Whereas the labels thereon are frequently false and misleading; and

Whereas the presence of poison or a deleterious substance in or on foods or cosmetics may be injurious to health and should therefore be prohibited; and

Whereas in the advertising of drugs and like products there is frequently a claim for a specific cure of diseases when the said article is merely a palliative:

Be it resolved, That the Kentucky Federation of Women's Clubs earnestly consider the proposed bill (the Copeland bill, S. 2800) and work for the passage of the principles contained therein.

Resolution Adopted by the Ohio Federation of Women's Clubs, at their Thirty-eighth Annual Convention, Cleveland, Ohio, April 10–13, 1934

Whereas the Pure Food and Drug Act, passed 27 years ago, though excellent in its day, fails to meet present conditions;

Whereas problems of health and economy are of paramount importance in these strenuous times;

Whereas the protection of the health of the family and financing the family's needs are primarily the woman's job. Therefore,

Be it resolved, That the Ohio Federation of Woman's Clubs, in convention assembled, endorse the following, as principles to be embodied in any new Pure Food and Drug Act:

1. Truth in advertising in newspapers, periodicals, or over radio.
2. Penalties for false remedial claims for drugs and remedies.
3. The inclusion of cosmetics.
4. The abandonment of the requirement of proving that the defendant knew the claims to be false.
5. The requirement of legal standards for traffic in foods.
6. The requirement that labels on foods and drugs disclose sufficient facts to enable intelligent buying.
7. Inspection of factories.

Be it further resolved, That a copy of this resolution be sent to Senator Copeland and to each Congressman from Ohio.

Resolutions Adopted at the Eighteenth Annual Conference of the South Central States Food, Feed, Drug, and Health Officials' Association, at Louisville, Ky., May 8, 1934. Officials Representing Kentucky, Tennessee, Alabama, Louisiana, Mississippi, and Texas were Present at this Meeting

Whereas, there is now before Congress a bill, S–2800, which is designed to protect the public from the damages of adulterated, misbranded, poisonous, or dangerous foods, drugs, cosmetics, and appliances, and the members of this association are well cognizant of the need of such a bill, therefore, be it

Resolved, That this association approve this bill and urge its passage by the Congress of the United States; and be it further

Resolved, That the secretary of this association be instructed to inform Senator Copeland, of New York, of this action by this association; and be it further

Resolved, That each member of this association notify the Senators and Representatives of his State and urge them to further the passage of this bill at an early date.

Statement on the Federal Food and Drug Bill, by Charles D. Howard

The anticipated bombardment on the part of the well-known "interests" against the pending much-needed Federal food and drug law revision has been full force for some time. Those of us who have reason to be familiar with the methods of these adversaries and who have a knowledge of the history back of the eventual passage of the original act of 1906—a history of 40 years of fighting for this pioneer accmplishment—may well feel apprehensive as to the outcome at this time.

The annual legislative compromise and with a number recognizably weak provisions to start with—albeit its enforcement has served to effect profound reforms of the one-time wide-open situation—this law has at length become inadequate to cope with the various changed situations and altered methods and practices which have come about in industry during the past quarter century. That there is imperative need of substantial revision there can be no question.

THE EVOLUTION OF MANY MINDS

In the press one finds a favorite editorial belittlement of this bill in the reference to it as being the pet conception of "Bolshevik theorist", and one is led to infer that it is exclusively the brain child of that professorial member of the President's "brain trust" whose name it happens to bear. That the present Assistant Secretary of Agriculture is its enthusiastic champion, and that he had a prominent part in its final preparation is not to be disputed. For his active collaboration praise is due.

But it is as well the handiwork of others. Made a part of the administration program and known to have introduced by express direction of the President, after having received the careful scrutiny and approval of the Department of Justice, it is nevertheless a fact that this measure has been in process of evolution for some years. It is the final product by no means of the ideas of one man, but of a number who each have had some part in shaping it—men who have had long experience in food-law enforcement, who are all too well acquainted with the manifold deficiencies, defects, and weaknesses which characterize the existent act, and who have time and again found themselves hampered in attempting to accomplish even the things for which the present law is supposed to provide, to say nothing of those things for which it ought to provide but does not.

EXISTENT LACK OF COSMETIC CONTROL

To cite one outstanding instance of the considerable number of the latter—which can also serve as an instance of the multi-authorship of the bill, in that this writer had some small part in shaping this feature—there is no provision whatever in the present law for the highly important class of preparations known as cosmetics—articles closely allied to drugs and of universal and every-day use on the person. Although this is a gigantic industry, with sales running into hundreds of millions of dollars annually, and although there are here involved great potentialities for both personal injury

and fraud, second in this respect only to remedial preparations, the makers and distributors have always enjoyed complete immunity from regulation. Against all attempts at State legislation the industry has invariably advanced the long-familiar and plausible-sounding alibi that national legislation must come first. "Let a Federal bill be introduced and we'll support it"—a tongue-in-cheek promise that is now being given active repudiation.

A short-sighted attitude, because a great majority of cosmetic preparations are above criticism as to composition, and hence the reputable maker should welcome the proposed house cleaning. In this connection, it has been well said that "laws are made and enforced for the control of the minority which, unless controlled, may damage in serious ways both consumers and honest competitors." A stumbling block here is in the fact that the industry, or no small part of it, craves continuance of the prerogative of advertising in a manner to delude the purchaser.

STANDARDS OF IDENTITY

It is being made to appear that the provision which would confer upon the Secretary of Agriculture authority to set up standards which would have the force of law is to give this official "czaristic powers." Arbitrarily and by executive fiat, it would seem, he could dictate a given standard overnight. Yet the food industry well knows that no such autocratic action is contemplated or would be involved. This writer knows whereof he speaks, as it happens that for the past 15 years he has had the honor of being a member of a Federal board which is charged with the duty of formulating food standards. The proceedings to this end are anything but hasty or ill-considered. The particular industry concerned is extended a hearing—not infrequently several of these may be held on a single topic—at which those interested are invited to appear and express their views, the facts and arguments presented being thereafter profoundly considered by the board; whereupon a tentative standard is developed and sent out to the industry for its comments and a possible further hearing. The standard eventually evolved must next receive the careful scrutiny of the Department's law officer, and not until then is it finally promulgated by the Secretary. Nothing could be fairer. This method has the great advantage over the legislative one that in the event the need for some modification of a standard is made apparent, this can be effected without incurring the time and expense necessitated by a special act of Congress.

The objection to the present standards is that they do not have the force of law; they are advisory only and serve to the court merely as guides. Hence, where a respondent chooses to ignore them in his defense, the Government is placed to great expense in each such case by reason of the necessity of presenting expert testimony in their support. This means a serious handicap to enforcement, and one which is quite unnecessary, because practically never is one of these standards upset in the court proceedings.

HEALTH FEATURES

From the standpoint of public-health protection the bill includes a number of valuable provisions not contained in the present law, provisions of various and wide application. To cite one example, at the present time there is no authority for control of the sanitary conditions of food-producing establishments, other than meat. It makes no difference how extensive the abuses may be; the only recourse against these is to prove by objective examination of the food product itself that this is unclean or decomposed. There are various articles being sold as food which are, per se, hazardous to health and the production and distribution of which should be under careful control. Such foods at the present time are not in violation of the act, although obviously dangerous to health. As proposed, food will be deemed adulterated if it is of such character or origin that its consumption entails a health hazard.

SYNTHETIC LIQUOR UNDER REPEAL

With the advent of prohibition repeal, we are already finding, as was to be expected, gross abuses in connection with the composition and labeling of liquors, abuses for the control of which the present law is ineffective. Space does not permit of the enumeration here of the various other much-needed features embodied in this bill and which are not covered, or are not adequately covered, by the existent act.

FALSE AND DECEPTIVE ADVERTISING TABOOED

An outstanding feature of this bill and the one that is now causing a prodigious hullabaloo in certain quarters is the seemingly reasonable proposal that we shall have truthful advertising of foods, remedials, and cosmetics. Only heaven and the enforcement officials have any adequate appreciation of the present pernicious and wide-spread abuses in this respect and of the crying need for reform. Yet, with peculiar appropriateness—with an opposition running true to form—this proposal is being met by a highly organized campaign, the weapons of which are derision, sneers, appeals to prejudice and ignorance, misrepresentation and downright lying.

This is not to say that all of the opposition is of this character. Much of it, as is the case with all control legislation, arises from honest misapprehension. So far as the food industry is concerned, this is now for the most part on an honest basis, and the same is true of the manufacture and distribution of official pharmaceuticals. The various elements in these industries are for the most part very well intentioned. They are disposed to do the right thing, and thus far they have voiced comparatively little opposition.

ACTIVITIES OF PROPRIETARY INDUSTRY

As might be expected, the great hue and cry is emanating from the proprietary remedy and cosmetic interests. It is these that mainly are to be held responsible for the highly organized and cunningly conceived propaganda now being so extensively disseminated. Doubtless there is by now not a newspaper or periodical publisher in the land who has not been circularized and importuned with requests that he do his part in dexterously indicating to his readers that while this bill is "lofty in purpose" it is utterly vicious in its actual proposals and calculated to be destructive of industry. That many of these publishers have been threatened that enactment would mean serious curtailment of income from advertising is no secret.

ADVERTISING THE LIFE-BLOOD OF THE NOSTRUM INDUSTRY

In this connection Mr. W. G. Campbell, Chief of the United States Food and Drug Administration, points out that "much of the opposition to this bill seems to be buoyed up by the unflattering assumption that broadcasters and publishers can be blackmailed into support of the patent medicine crowd by threatening them with loss of advertising." Arguing that "This is nonsense," Mr. Campbell forcefully reminds the public that "these manufacturers cannot stop advertising, and they know it. Advertising is the life-blood of their business. They will have to go on with it at the cost of being truthful."

One might, indeed, infer from the tone of some of this propaganda that the advertising industry is in peril of extinction. If it were so that advertising for its effectiveness must invoke the elements of falsity, deceit, and dissimulation, then it would deserve that fate. But happily it is not so. Actually there is no sound reason why the consuming public should be told other than the truth about the products being offered it. The nostrum maker has no right to assume that he is privileged to hoodwink the suffering and the gullible, or that these are his legitimate prey. The notion that advertising must be delusive in order to create sales is an old one, finding embodiment in some degree in much of the offerings of national scope and which are tacitly sanctioned by even the higher class of periodical publishers and radio broadcasters.

SCARING THE PUBLIC

A powerful motive back of very much of this advertising is the creation of apprehension about one's health. There is much twaddle and meaningless claptrap about germs, vitamins, constipation, the perils of stale coffee, and means for the avoidance of cold-catching—stuff that is flagrantly deceptive and unwarranted on the basis of scientific fact. This the public readily swallows, as it is intended that it shall.

ESSENTIALS OF DISHONEST ADVERTISING

It requires no great acumen to understand the test of what constitutes dishonest advertising. Where the language is such as to attribute to an article a quality or value that it does not possess, such that the public—generally ignorant of such matters—is led to purchase it under a misapprehension as

to its merit or of what its use actually is likely to accomplish, this form of sales promotion is an imposition upon the reader or listener and deserves to be checked.

The interests here concerned are adept in the art of specious reasoning and it is significant that most of the objection advanced has involved an effort to make it appear that the Government's activity here would mainly be confined to the pursuit of trivialities, of divesting the language of advertisements of those expressions of "trade puffery" which are innocent enough for the reason that they fool no one; with the result that all advertising would be drab and colorless. Actually, the opponents well know that there is no such intent. They know perfectly well where the line will and should be drawn. There is a distinction between deception and mere fulsomeness of praise.

It has been predicted that when or if this bill is favorably reported from committee, it will not be without drastic revision. This does not augur well. It is to be hoped however that its friends (which should mean every consumer) will see to it that its essential provisions shall remain intact.

Senator CLARK. Mr. Craig.

STATEMENT OF HUGH CRAIG, MANAGING EDITOR, OIL, PAINT, AND DRUG REPORTER, AND ASSOCIATE EDITOR, THE DRUGGISTS CIRCULAR

Mr. CRAIG. My name is Hugh Craig. I am managing editor of the Oil, Paint, and Drug Reporter and associate editor of the Druggists Circular, publications in the chemical, drug, cosmetic, and related industries, published at 12 Gold Street, New York.

I appear in representation of the long-existing interest of these publications, with which I have been associated for more than 29 years, in the promotion of honest and efficient pharmacal service to the public. I appear also for myself; I am a registered pharmacist and have been connected with the drug business for more than 37 years.

The Oil, Paint, and Drug Reporter is an industrial publication rather than a trade journal. It is concerned chiefly with matters pertaining to the production, distribution, and industrial consumption of raw and intermediate materials comprised by the general classifications of chemicals, oils, and drugs. It has been published continuously for more than 63 years.

The Druggists Circular is a publication for retail druggists. It has been published continuously for 78 years, and was a pioneer in the fight against quackery in the drug business. Prior to the enactment of the Federal Food and Drugs Act of 1906, the Druggists Circular made many original disclosures of quackery, its early articles in this respect having to do with a number of so-called "medicines" then popular, such as Scotch Oats Essence and Radam's Microbe Killer. It also published disclosures by others and continuously and vigorously condemned quackery. It was from the files of the Druggists Circular that the early "muckrakers" in the medical-nostrum field drew many of their data.

In my editorial capacity and as an individual I have been and am now an outspoken advocate of honesty and honor in the drug industry. I am a firm believer in the purpose of the Federal Food and Drugs Act, although I have not always agreed with the policies and practices of its administration. I believe that the act should be extended to include cosmetics and advertising, and that it needs to be revised in certain respects to make it more efficacious in its application to drugs.

I do not support S. 5—Committee Print No. 3—as a means of accomplishing the necessary and desirable extension and revision of the act. I believe that this bill falls short of adequacy in certain respects and that it objectionably exceeds that which would be adequate in others.

I believe that the necessary revision of the Food and Drugs Act would be more satisfactorily accomplished by amendment of the existing law than it would be by a complete rewriting of the statute. This belief is based on the desirability of retaining the value of regulations and court decisions under the act and of not disturbing unnecessarily the correlation of State laws of similar purpose.

I consider S. 5—Committee Print No. 3—objectionable in its philosophy of legislation in that it falls short of necessary completeness in its definitive provisons and purposes extensive delegation of legislative authority to administrative functioning.

I feel also that, in placing the supervision—control, if you will—of advertising in the Department of Agriculture, rather than in the Federal Trade Commission, which already has certain authority in this respect, S. 5 would set up dual and conflicting administration, the effects of which on efficient enforcement would be aggravated by departmental jealousies. I am not impressed by the argument that the Federal Trade Commission could not be appropriately empowered in this respect, and I do not believe that the alleged inadequacy of the Commission's equipment could not be remedied.

I leave to others in largest part discussion of the legal aspects of the method of revision presented in S. 5. Necessarily, I must touch upon these aspects to some extent in the consideration of the practical aspects of this measure in the comment that follows. Because of the limitation of time this comment is necessarily sketchy. It ties in with the copy of the bill and therefore should be adequate to the needs of this hearing. I shall be pleased to elaborate on any point as may be desired by members of the committee. I ask permission to file later a brief in more detail.

The definition of the term "drug" is unnecesarily confused and potentially restricted with respect to the purposes of the act by the inclusion—page 2, lines 6 and 7—of the phrase, "and not for the regulation of the legalized practice of the healing art."

Whether the purposes of the act, as stated in the title, be directed to the regulation of interstate commerce in the articles to which it is made applicable, or to the protection of the public health with respect to these articles, the phrase referred to is objectionable from the standpoint of efficacious enforcement. The right of a physician to use such drugs as he may desire, or to use placebos when he so desires, should not be curtailed; but I believe that it was abundantly shown in the hearings on the predecessors of this bill in the preceding session of Congress that duly legalized and doubtless fully qualified doctors of medicine engage in practices which logically come within the purview of this act and therefore should be subject to the provisions of the act.

I suggest the deletion of the phrase "and not for the regulation of the legalized practice of the healing art." I consider the presence of this phrase as gratuitous as would be a similar reference to the practice of horseshoeing, correlated to the inclusion of certain devices

in the definition, or to the laundering of wash cloths which by reason of the proposed definition of cosmetics, would be required to be sanitary and free from filth.

I believe that the definition of the term "drug" is unnecessarily and objectionably comprehensive in its inclusion of substances and preparations recognized in the official compendiums when these are not intended or sold for a medicinal purpose. I suggest the addition, following the word "thereto" in line 10, page 2, of the words, "and intended or sold or offered for sale for use as or in a medicine for man or other animals." It needs but be mentioned that many substances and preparations covered by this clause in the definition are intended and sold for various purposes other than medicinal use.

I urge the deletion of the word "devices", from clauses (2) and (3) of the definition, lines 11 and 13, and the inclusion of a separate classification for such devices as should be reached by the act. This would entail the necessity of a separate definition, with the endeavor by proper phraseology to exclude such preventitives as dog muzzles, rubber overshoes, and flannel underwear. I do not believe in doing violence to the English language—and a device is not a drug.

The suggestion I have made would entail also the inclusion of the word "device", with the word "drug", in all subtitles and text wherein it is commendably sought to prevent the misbranding of devices. I do not believe that the purpose of the act comprises prevention of adulteration of devices, even to the extent of the declared adulteration by radio advertising about which I shall have something to say later.

I suggest the addition of the words "or sold, or offered for sale", in connection with the word "intended", in clauses (2) and (3) of the definitions of the term "drug" and in the definitions of the terms "device" and "cosmetic." The word "intended" has several shades of meaning, and many articles are sold or offered for sale for purposes for which they are not intended in the sense of some of these shades.

I suggest the clarification of the definition of the term "cosmetic" so as to exclude devices such as artificial teeth, wash cloths, hair brushes, permanent wavers, and—who knows what fashion may dictate at some early date—those which are or may be regarded to be necessary to enhance the appearance of the contour of the human form. Devices of a purely cosmetic character, masks, mittens, and the like, can be included by rewording the definition of the term "cosmetic", paragraph (c), page 2, to read somewhat as follows:

> (c) The term "cosmetic" includes (1) all substances and preparations intended or sold or offered for sale for external or orificial application in producing a cleaner or otherwise improved or altered appearance of the person; and (2) all devices intended or sold or offered for sale for use in improving or otherwise altering the appearance of the skin.

I suggest the addition at the end of paragraph (f), page 3, line 2, of the words "in the singular and the plural."

I urge the inclusion of the word "commercially" between the word "opinion" and the word "disseminated", in paragraph (j), page 3, line 15. People will talk, or write. Public expressions of fact or opinion cannot be confined within the responsibilities of a person who is commercially interested in the article with which

these expressions have to do, and to penalize the volunteer utterer of such fact or opinion is to violate the right of free speech.

I believe that it is unnecessary for the purposes of the act to define the term "medical profession" or the term "medical opinion." Certainly it is unreasonable to define these terms, as this bill does, paragraph (k), page 3, lines 17 to 23, so as to exclude the authoritative opinion of pharmacologists, pharmaceutical chemists, and physiologists. These scientists are not licensed practitioners of any branch of the healing art, but they are qualified to know therapeutic effects much better than are licensed nurses, osteopaths, chiropractors, chiropodists, and the like. It is unreasonable to set up criterions of opinion, as this bill does in lines 21 to 23, page 3, which differ widely among the several Federal jurisdictions. It is not constitutionally permitted to set up different laws for different sections of the United States.

Great violence is done to the English language by the provision in section 401 (a) (1), page 13, lines 7 and 8, which declares that a drug will be adulterated by statements made in the labeling or advertising thereof. Adulteration is wholly a matter of composition, not of description. The purpose of this provision is a necessary and a commendable one, but this does not justify an attempt to give Congress authority to pervert the accepted meaning of common words. Congress has sought, in the Naval Stores Act, for example, to restrict illogically the use of common English words. I do not believe that even that restriction, which makes illegal the use of such common designations as "rosin oil", would stand the test of the courts—it has never been tested. I am certain that the perversion of the word "adulterated" to include what is clearly misbranding would not stand in court.

To avoid weakening the enforcement of the act, clause (1) of paragraph (a) of section 401, page 13, lines 7 and 8, should be transferred to section 402, page 15, devoted to misbranding. It is possible to provide an efficacious remedy against the form of misbranding at which this clause is directed. In truth, the bill makes no mandatory distinction between even minor misbranding and adulteration in respect of the procedure of enforcement. Some such distinction would be reasonable. Misbranding that is imminently dangerous to public health should be dealt with as severely as adulteration; but, no law should be unreasonable in its provisions or anomalous in its language for the mere purpose of making the job of its enforcement easier.

I take it that the word "decomposed" in line 10, page 13, has no reference to products of intentional decomposition, chemical, or otherwise. Some clarification of wording seems desirable. I suggest the substitution for the word, "decomposed" of the word "rotten."

Clause (3) of paragraph (a) of section 401, page 13, lines 10 to 13, presupposes the setting up of a system of factory inspection. Its retention in the act necessarily would depend upon the establishment of such a system.

Clause (5) of the same paragraph, lines 15 to 18, does not distinguish between a coal-tar color used for purposes of coloration and one that is used as a medicament. Because standards are otherwise set up for medicinal colors and their further standardization is to be

expected, a distinction in the respect alluded to should be made by inserting in line 16 after the word "contains" the words "for purposes of coloration" and making a similar addition to section 403, page 20.

Paragraph (b) of section 401, beginning at line 19 on page 13, is one of the most important, as well as most controversial, provisions. Official drugs fall into three categories: (1) Crude, natural products, the effective strength of which cannot be standardized in production; (2) chemical substances which can be standardized in strength and purity in production; and (3) galenical preparations which present the problem of variations in strength to meet different requirements of the physician, and the additional problem of improvement through variation of formula or process. The wording of this paragraph does not clearly meet the needs of conditions with respect to drugs of the first category; although this shortcoming is somewhat remedied by clause (2) of section (d) on page 15. A definite reference to identity in paragraph (b) would be an improvement.

The delegation to the Secretary of authority to make tests for the application of official standards opens a legal question which I shall not discuss; but, the possibility of thus establishing two different standards should be avoided.

I fully support the "variation clause", lines 10 to 12, page 14, of paragraph (b). Permissible variation is necessary, not only with respect to crude, natural products, but also to chemical substances and galenical preparations. It is highly necessary, however, that the label tell the truth about the identity, strength, and purity—I feel that quality is a composite of these. There must be standards, but these standards must be valid, and inflexibility is not compatible with validity and is tantamount to the granting of a monopoly in the use of common names.

It is strange to me that, having recognized the necessity for permissible variation in paragraph (b), the bill practically invalidates this permission by the terms of paragraph (d) on page 15. Paragraph (d) is unnecessary. Clause (1) is unreasonably inconsistent with paragraph (b), and the purpose of clause (2) can be achieved by introducing in paragraph (b) a requirement that the identity of a drug shall not differ from that of the definition in an official compendium.

I believe that certain changes in the phraseology of paragraph (a) of section 402, page 15, were agreed upon in the hearing March 2. As I understand the changes the objectionable stringency of the paragraph has been mitigated. These changes are not before this hearing. The provision as it stands could not be complied with, because the complete sustenance required is an impossibility. In spite of the minor change that would result from acceptance of the suggested wording, there remains a serious question of the validity of the paragraph by reason of its acceptance of certain facts and opinions as criterions. The definition of "medical opinion" in the bill increases the seriousness of this question.

Scientific and medical opinion changes. A preparation condemned roundly by accepted medical opinion twenty-odd years ago, largely because of inability to determine the basis of certain claims made therefor, has lately become quite popular with physicians practicing a specialty. There is reason to believe that, in the light of the vitamin theory, the condemnation of extractive preparations of cod-liver oil a few years ago because of the opinion that the efficacy of the oil depended wholly upon its peculiar fatty structure, was not sound.

The bigger question is one of constitutionality, and I feel that I should depart from my general purpose to leave to others the discussion of the legal aspects of the bill, to say that the delegating to utterers of scientific or medical opinion the authority to define the scope and application of a Federal statute is of doubtful validity. The bill clearly makes it an illegal act to say something about a drug which is not in accord with what others, unnamed and but sketchily defined in a generic sense, may opine in the matter.

In view of the decision of the Supreme Court of the United States with reference to section 9 (c) of the National Industrial Recovery Act, this proposed delegation of authority must be essayed most cautiously. It is well to search out the answer to the question propounded long ago by Pontius Pilate—"What is truth?"—but the determination of facts is a matter for the courts. Certainly unknown facts cannot legally be evaluated in advance of their adduction. In the absence of an adequate enabling clause in respect of findings of fact, the proposal of poorly defined and unknown criterions of truthful therapeutic claims is open to serious question.

Whether more harm or good is done by informing the public that a drag is a habit-forming narcotic or hypnotic is an open question. Its seriousness is somewhat lessened by the restrictive legislation of the several States with respect to such drugs, and it cannot be doubted that it accomplishes some good. I believe, however, that any list of such drugs as it may be deemed desirable to have disclosed should be complete in the bill. Otherwise the use of a valuable new drug may be seriously handicapped by reason of its proscription by regulation on the basis of incomplete evidence or inadequately supported suspicion. I urge the deletion from paragraph (d) of section 402, page 16, of the phrase, lines 13 to 16, "or any other narcotic or hypnotic substance which has been designated as habit forming by regulations provided by sections 701 and 703."

The value of the disclosure of the therapeutically active components of a drug, as proposed in paragraph (e) of section 402, page 16, is also an open question. The benefits of such disclosure to the public are not clear. Knowing the name of a drug, without knowing anything else about it, does not equip any person with ability to select appropriate or safe medication.

As a pharmacist I know that the human propensity to display that little knowledge which is a dangerous thing is in no connection more avidly manifested than it is with respect to a supposed knowledge of the efficacy of certain drugs. Inadequate knowledge of this sort, gleaned from a list of the components of a drug, can easily result in the dangerous use and recommandation of one of these components. Physicians recognize this fact in their writing of prescriptions. Self-medication by the public can be far better safeguarded when the furnishings of drugs for this purpose is left to those whose activities can be controlled under Federal and State

laws than it can be when everybody is enabled to select drugs and determine the dosage thereof for the treatment of himself and all his friends.

In addition to being commercially detrimental in its disclosure of trade secrets, for the protection of which no effective alternative has been adduced, the printing on the label of the names of the components of a drug would open the way to serious jeopardy to the public through the manufacture and sale of improperly compounded imitation products.

The reason for setting up special provisions for germicides, bactericides, disinfectants, and antiseptics in paragraphs (j) and (k) of section 402, pages 18 and 19, and not similarly treating other classes of drugs, is not clear to me. The adequate evaluation of these specified drugs can be based on relevant facts, as is done with respect to all other classes of drugs. Due regard should be had for the fact that the terms by which the drugs of this specially treated class are designated are practically synonymous to the public. These drugs should be in fact what the public expects them to be, and no exemption should be made from strict adherence to the import of the designation no matter what the use for which a so-called "antiseptic" may be designed.

With respect to the adulteration of cosmetics, page 20, section 501, I offer the same criticism to paragraph (a) as I offered to the similar provision with respect to drugs (page 13, section 401 (a) (1); that is, what is defined as adulteration is in truth misbranding. I urge again that this paragraph be transferred to the proper section on misbranding, section 502, page 21.

The criticisms which I offered to clauses (2), (3), (4), and (5) of paragraph (a) of section 401, page 13, with respect to drugs, I offer respectively to paragraph (b), (c), (d), and (e) of section 501, page 21, with respect to cosmetics. Definite provision should be made legally to meet the purpose of the original, now deleted paragraph (b) of section 501, page 21.

The questions I raised with reference to paragraph (a) of section 402, page 15, I raise also with respect to the concluding sentence in paragraph (a) of section 601, page 24, including the revised phraseology which I believe has been accepted. I feel that such blanket acceptance of criterions is not valid.

Paragraph (b) of section 601, page 24, raises a question of fact. I join wholeheartedly in the condemnation of any claim to cure or substantially to benefit a sufferer from a serious disease by self-medication, by unintelligent or otherwise inadequate medication, or by distant treatment. I do not agree in the premise that medication has no therapeutic effect or value in connection with the treatment of serious diseases—those enumerated in the paragraph and others. The effect of medication may be solely alleviative, but relief from coughing or from symptomatic pain is a necessary and desirable adjuvant to the scientific, adequate treatment of serious diseases, because it aids the sufferer to rest, and rest is an essential.

It is a human expedient to attempt to prohibit that which cannot readily be controlled. But, facts are facts, and the setting up of fallacious or unsubstantiated beliefs as facts is not sound lawmaking. It is necessary lawmaking to establish most rigid means of

preventing the exploitation of the seriously ill. But this does not justify the stating as a fact of a belief that drugs are without "any therapeutic effect" in the treatment of certain diseases.

If it shall be deemed necessary to specify certain diseases for the purpose of preventing unconscionable exploitation, these should be named in the bill. It is to be presumed that the healing art will progress, rather than retrogress, in its therapeutic ability to combat serious diseases. I offer only a suggestion of careful procedure. I believe that the Congress can, and I hope that it will, construct an adequate safeguard against the misleading of the seriously ill. I suggest that it avoid the possibility of meeting in the enforcement of the act an insurmountable, factual obstacle or a defense based on the alleged implication of the act that only the diseases enumerated are proscribed in respect of the making of unwarranted therapeutic claims.

Senator COPELAND. I assume you approve the limitation to those diseases which are obviously the ones where there has been an exploitation of the public?

Mr. CRAIG. No.

Senator COPELAND. You want to leave them out entirely?

Mr. CRAIG. I see no sense in putting them in because I make the point here that naming certain diseases may face the administration of the act with a defense that, because another disease was not named, they can say anything they want to about the therapeutic value of a drug in it.

The general administrative provisions contained in chapter VII of the bill, beginning on page 25, largely present legal aspects to which I do not purpose to address myself. There are among these, however, certain practical aspects on which I shall comment briefly.

I do not subscribe to the philosophy of legislating by administrative functioning, with or without the benefit of industrial advice. The definitive provisions of a statute should be adequate in themselves. In the event that, and to the extent that practical advice shall be deemed to be essential—as it is essential—to the adequate enforcement of the act, provision should be made to get the best possible advisers, and the advisory bodies should be adequately and equitably representative of knowledge of the practical aspects of administration. Theoretical—scientific, if you will—advisers have not unquestionably proved their adequacy to administrative needs in various governmental undertakings.

It was suggested at the hearing March 2 that a panel be created for the food industry, so that the advice of persons familiar with a matter in hand would be available. The suggestion is an excellent one. I urge its adoption with respect to advisory representation of the drug and cosmetic industries also.

I do not presume to say that factory inspection, as proposed in section 707 (p. 32), is not necessary in the drug and cosmetic industry. I accept the findings of the Food and Drug Administration in this respect. I do believe, however, that paragraph (b) of section 707 (p. 33) should be rewritten as was suggested in the hearing March 2. In the form in which it appears in S. 5 (Committee Print No. 3), this paragraph unwarrantedly would subject the manufac-

turer of a wholly legal article to punishment that is most cruel and unusual. Compelling inspection by due process of law is a sufficient and legal method of dealing with refusals.

In keeping with suggestions hereinbefore made, I urge the insertion of the word, " commercially ", before the word, " disseminated ", in paragraph (4) and (5) of section 708 (a) (p. 34, line 22, and p. 35, line 3).

With respect to seizures (sec. 711, beginning on p. 41), I submit that a specific, low limit should be placed on the number of seizures that may be made because of allegations of misbranding which represent only differences of opinion with respect to relatively innocuous therapeutic claims. In cases of allegations of adulteration or of misbranding in respect of facts or otherwise imminently dangerous to health, the number of seizures might well be limitable only by due process of law on the basis of relevant facts.

Nothing is gained, or can be gained, by the unnecessary harassment of the industry by a multiplicity of condemnation proceedings. The proposed consolidation of such proceedings in one jurisdiction located conveniently for the claimant is a commendable manifestation of reasonableness. Nothing would be lost to the enforcement of the act by a further step joining the several seizures as separate counts in a single action.

It is neither reasonable nor necessary, as I see the purpose of the act, to authorize seizure forthwith, without the preliminary formality—let us say—of a libel of information. The unreasonableness of this provision (sec. 711 (a), p. 43, lines 2 to 7) is aggravated by the first clause in the bill's definition of adulteration of a drug or a cosmetic.

I reiterate my earnest belief in the necessity and desirability of making the Federal Food and Drugs Act more comprehensive with reference to cosmetics and to advertising. I believe that the statute has vitiating shortcomings with reference to drugs, which should be remedied. I believe that the act can be made adequate by amendment. I further believe it to be practicable, and I aver that it is most desirable, so to construct and so to set a rat trap as not to jeopardize the household terrier who is working diligently to rid the place of rodents.

Senator CLARK. Dr. Little.

STATEMENT OF DR. ERNEST LITTLE, PRESIDENT AMERICAN ASSOCIATION OF COLLEGE OF PHARMACY

Dr. LITTLE. Mr. Chairman and gentlemen of the committee, my statement is exceedingly brief. As president of the American Association of Colleges of Pharmacy, I am very happy to point out briefly some of the reasons why our association is in favor of Senate bill 5, print 3, and why our members are anxious to assist in promoting its speedy passage.

We are interested, as consumers, as a group, who feel more than ordinary responsible for the protection of the great body of consumers, and as a group who each year send into the profession of pharmacy young men and women who are charged with the preserving, handling, and dispensing of drugs and medicines.

We feel that we are fortunate in being in a position where we can judge this bill exclusively from a standpoint of public health and public welfare. That is our sole criterion and our only measuring stick. We, of course, feel that these necessary regulations should be effected with the very minimum amount of hardship upon the legitimate, conscientious manufacturer.

We approve of extending the bill to cover cosmetics as now provided in this bill.

We feel that the portion of the bill covering foods has been greatly strengthened and improved.

Our chief interest and main responsibility is in that portion of the bill dealing with drugs.

We heartily approve of that part of the bill, page 13, lines 10 to 15, which declares a drug to be adulterated which is prepared, packed, or held under unsanitary conditions whereby it may have been contaminated and rendered injurious to health. We approve of section 707 (a), page 32, which gives the power of factory inspection to the Secretary of Agriculture. Without this provision many of the provisions of the law, particularly that dealing with unsanitary conditions, would be greatly weakened.

We heartily endorse section 601 (a), page 23, dealing with false advertising. Today statements made in advertisements are believed by none other than the most gullible. Honesty in advertising should prove helpful to advertising concerns, to the large number of conscientious manufacturers, and is a most necessary protection to public health. With the sort of regulations in operation which restrict all representations concerning the effect of a drug to such statements as can be sustained by demonstrable scientific facts or substantial medical opinion, the public will place more confidence in advertising statements, and there should be more incentive for honest manufacturers to make the value of their products known through various advertising mediums.

We believe that the enforcement of this act, as pertaining to advertising, should not be vested in the Federal Trade Commission but in the Department of Agriculture, as now provided in chapter VII, section 701, page 25. The Department of Agriculture has the equipment and personnel which is so essential to adequate enforcement of the regulations set forth in chapter VI, section 601, pages 23 and 24. In the interest of both efficiency and dispatch the Department of Agriculture should be assigned this responsibility.

We have not gone on record as favoring the variation clause, section 401 (a), lines 10 to 18, page 14. We feel that the bill would be strengthened by omitting this provision. To state on its label that a drug varies thus and so from the standards of an official compendium means very little to the average purchaser. It affords him little or no protection but may even lead to confusion.

I would like to ask Senator Copeland if section 402 (a), page 16, applies to physician's prescriptions compounded by registered pharmacists?

Senator COPELAND. There is a feeling on the part of the doctors that it should be made more definite in the bill. There is no intent that it should apply to prescriptions.

Senator CLARK. What do you mean by " made more definite ", Senator?

Senator COPELAND. This does not apply to doctors. What is your view of that, Doctor?

Dr. LITTLE. We feel it should not be necessary to place the warning "may be habit forming" on such prescriptions.

Senator CLARK. Why is that, Doctor? Why should not it be placed on a prescription as much as on any other preparation?

Dr. LITTLE. We feel it would serve only to confuse or frighten the patient.

Senator CLARK. It might keep him from taking it, might it not?

Dr. LITTLE. It would perhaps cause him to refrain from taking the medicine; yes, sir; which is essential to his well-being. The prescription has been carefully drawn up by the physician with the individual needs of the patient in mind, and for that reason we feel it should be exempted.

We feel that section 402 (e) (2), page 16, has been somewhat weakened by making it unnecessary to disclose the quantity or proportion of each active ingredient.

There are other details in which the bill does not entirely agree with what we feel it might best be. We wish it made quite clear, however, that in the main the criticism which we are offering to this bill is most favorable. We believe that its passage would mark a big step forward in pure food and drug legislation. For this reason we are quite willing to overlook those parts of the bill which please us least and to place upon it the whole-hearted stamp of approval of the American Association of Colleges of Pharmacy.

We sincerely hope that it may be enacted into law without undue delay. We feel very certain that public health and public welfare would be more adequately protected by the passage of such legislation.

Senator COPELAND. Thank you, Doctor.

Senator CLARK. Dr. Reddish.

STATEMENT OF DR. GEORGE F. REDDISH, NATIONAL COMMITTEE OF MANUFACTURERS OF ANTISEPTICS

Dr. REDDISH. Mr. Chairman, I represent the National Committee of Manufacturers of Antiseptics.

For your information I would like to present briefly my qualifications for making the remarks which I have to make. In the first place I am Ph. D. in Bacteriology, Yale University.

Assistant in the Department of Bacteriology, Yale University, for 3 years.

Associate professor of bacteriology, Medical College of Virginia, for 2 years.

Bacteriologist in charge of testing disinfectants and antiseptics, Food and Drug Administration, United States Department of Agriculture, for 4 years.

Referee on standardization of disinfectants, American Public Health Association, for 5 years.

Chief bacteriologist, Lambert Pharmacal Co., since 1929.

Professor of bacteriology, St. Louis College of Pharmacy, since 1932.

I am a member of the Society of American Bacterioligists, member and fellow of the American Public Health Association, and member of the American Association for the Advancement of Science.

I am here today to discuss only two paragraphs of this bill, namely paragraphs (j) and (k) of section 402 which occur on pages 18, 19, and 20 of Committee Print No. 3 of S. 5. These paragraphs have to do with antiseptics and in them methods of testing are considered.

It happens that I developed the methods for testing antiseptics which are now employed by the Food and Drug Administration of the United States Department of Agriculture. It is for this reason I appear before you today to discuss especially the matter of testing this class of drugs.

At the outset I wish to state that I am not personally agreeable to having in this bill any special language—special legislation, if you please—covering this single class of drugs. It is, first of all, inconsistent with the remainder of this bill, since laxatives, headache remedies, anesthetics, canned ripe olives, and so forth, are not singled out for any such special legislative treatment. There is no reason, as I shall point out later, for specific language in this bill covering antiseptics, any more than is there reason for singling out any other group of food or drugs by name or class for special attention. There is adequate authority for Government regulation of antiseptics now under the present Food and Drugs Act of 1906, as I shall also point out later.

With your indulgence, gentlemen, I would like to give you a brief history of Government activities in the control and regulation of antiseptics under the present food and drugs law. I will carry you back to the very beginning.

The manner in which the present program of the Food and Drug Administration relative to antiseptics came about is rather interesting. When I came to the Department of Agriculture in 1924 my only duties were the testing of disinfectants. At that time antiseptics were not being regulated by any governmental agency. Our activities then covered disinfectants only. In testing and studying these disinfectants I was impressed with the fact that nearly all of these products which came to my attention included on their labels directions for use around dairy barns, cattle pens, pig sties, chicken houses, and so forth. In other words, I was spending the major portion of my time seeing to it that the farmers of this country were able to protect the health of their horses and pigs, their cows and chickens. During a quiet moment one afternoon I took a little time for serious reflection on the work which we were doing to benefit the American farmer and our efforts to protect the health of his farm animals. It occurred to me that we were spending a lot of time in protecting the farmers against substandard disinfectants so that his animals would enjoy good health, but we were doing nothing at all to protect the American public against worthless products sold as antiseptics. It seemed to me that the American public deserved at least as much consideration as the farmers' horses and pigs, cows and chickens.

With that in mind, I inquired as to whether or not we had the authority under the Food and Drugs Act of 1906 to regulate antiseptics for human use. I found that this authority was granted under the general provisions affecting drugs "for the cure, mitigation or prevention of disease." Antiseptics are drugs used for the cure,

mitigation, and prevention of disease. Provision for their control is clearly given in the present Food and Drugs Act.

Before actively entering upon this new project it was necessary first to develop suitable bacteriologic testing methods. It was my job to develop such methods. This was done as rapidly as possible and the methods were then published in scientific journals. You may be interested to know that when these methods were first published the only criticism of them which came to my attention was that they were too severe. I will not burden you with a discussion of those methods, nor will I point out to you the reasons why they are severe, except to say that approximately 350,000,000 of the most resistant of the nonsporing disease-producing germs—namely, Staphylococcus aureus, are used in the principal germicidal test. This is a very large number, far more than are found on the skin and mucous membranes, in cuts and abrasions, and even in actual infections as they occur under practical conditions. These tests were made severe intentionally so that the public would be assured of maximum protection.

While these methods were being developed in the laboratory, I made a thorough study of the definition of the word "antiseptic." I found that, according to the best authorities, this word has two meanings—namely, (1) to kill bacteria and (2) to prevent the growth of bacteria. These two meanings are in the literature and in the dictionaries, and, although there is objection in some quarters to this double meaning, there is nothing we can do about it. Many of our English words have more than one meaning. You may be interested to know, incidentally, that these two definitions of the word "antiseptic" suit our methods of test, or, more properly, our methods of test suit these two definitions.

My object in presenting these facts to you is to show you that the Food and Drug Administration is fully armed now with the proper authority for the control and regulation of antiseptics. Clear authority is given under the present Food and Drugs Act, standard methods are available for proper testing of these products, and there is adequate support from the literature, our current standard dictionaries, and from authoritive lexicographers, as to the proper definition of the word "antiseptic." May I present a reprint of a report by Dr. Austin M. Patterson, noted American lexicographer and consultant to Webster's Dictionary, covering these definitions.

While it is my opinion that there is no necessity for special reference to antiseptics in this bill, just as it has not been necessary to have such specific language in our present food and drug law, in order to exercise proper control over this class of products, this opinion is not shared by officials of the Food and Drug Administration. They have two reasons, I am told, for wanting in this bill special paragraphs covering antiseptics. One is to counteract the decision of Judge Chestnut regarding the meaning of the word "antiseptic" and the other is to legalize our present standard methods of testing antiseptics by including them in the law, or by making such reference to them as will serve the same purpose. As to the first reason, it is my opinion that this decision is no justification for including a definition of this word in the proposed law. After all, the decsion of Judge Chestnut represents but the opinion of one

person. It is inconceivable to me that the opinion of one man, even though he be a Federal judge, is sufficiently conclusive to stop or even seriously embarrass the Food and Drug Administration in the regulation and control of this class of drugs.

That is my opinion and it is shared by many others both in the industry and out of it. The officials of the Food and Drug Administration, of course, are in a better position to judge as to the necessity of such a definition appearing in the proposed law. If it will fortify their position in the valuable and necessary work they are doing in this field, a definition of this term should by all means be included in this bill. May I take the privilege of presenting to you a definition of the word "antiseptic" which seems to me would be adequate for this purpose.

When construing and enforcing the provisions of this act with respect to labeling and advertisements, the term "antiseptic" shall be deemed to have the same meaning as the word "germicide", except, however, in the case of a drug purporting to be, or represented as, antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

It is my understanding that this is not the only reason for paragraphs (j) and (k) as they occur in this bill. Both of these paragraphs include reference to standard methods of testing antiseptics and it is apparent that such references are made for a purpose. As a matter of fact, Mr. Campbell has repeatedly stated that the purpose of these two paragraphs in this bill is to obtain legal sanction for the present methods now being used by the Food and Drug Administration in the regulation of antiseptics. Again, I see no necessity for special reference to antiseptics in this proposed law, even for the purpose of legalizing, so to speak, our methods for testing drugs of this class. In the first place, it is not necessary to legalize them because they are already the official methods of test and have been designated so by the Secretary of Agriculture under date of October 15, 1931. These methods are described in United States Department of Agriculture Circular 198 and are officially designated here as the Food and Drug Administration methods.

In addition to the official nature of these methods of test, as designated by the Secretary of Agriculture, these tests are recognized as standard methods throughout the country, and are recognized and accepted as such by American bacteriologists generally. The methods of testing antiseptics used by the Food and Drug Administration are standard and they are official. I see no reason for including reference to them in this proposed law in order to secure further authority for making use of them in the control of these products.

Paragraphs (j) and (k) of section 402 of this bill purport to give to the Department of Agriculture legal sanction for the methods employed by the Food and Drug Administration for the testing of antiseptics. I have made a careful study of these two paragraphs and I fail to find these methods. If it is intended to include these methods in these paragraphs in order to make them legal, then the language of these paragraphs should be worded accordingly. This has not been done. The methods should be there if they are to receive legal sanction. As now worded, the language of these paragraphs is so indefinite that I would not know from reading them how to test

an antiseptic in order to be sure that it met with the requirements of the proposed law. I am expected to know how to test antiseptics to see whether or not they meet Government requirements. This is part of my job as bacteriologist for a manufacturer of antiseptics. It is part of my responsibility as chairman of the committee on antiseptics of one of our trade associations. The wording of paragraphs (j) and (k) leaves me completely in the dark regarding this all-important and fundamental question.

In paragraph (j), page 18, line 25, it is stated that antiseptics when "tested by a standard method" must have the germicidal effect of "a 1 to 80 dilution of phenol used by a standard method for 10 minutes at 37° C." You will note that we are given no light at all on what method will be used for testing the antiseptic and we can only assume as to exactly what method is intended must be used for the 1 to 80 dilution of phenol test. While it would be almost impossible to give complete details as to methods of test in these paragraphs, it would be quite simple to outline briefly the fundamental features of the tests to be employed.

I wish at this time to submit for your consideration substitute wording for paragraph (j) of section 402. The methods of test for the antiseptic and the phenol standard, you will note, are the same. Although the details of the method are not given, the fundamental features are outlined in specific language. This is important, or rather necessary, because it is only by this means that we can be assured that all of us will read and understand alike. The wording which I am suggesting represents a minimum standard and in no way limits the Food and Drug Administration officials in enforcing the provisions of this bill relative to misbranding and false advertising. By means of this test we can tell whether or not the product being tested is, or is not an antiseptic (germicide). None of our standard germicide tests go further than that anyway because it is not possible to interpret the results obtained by these methods as applied to each individual use recommended on the label of each such product. If the claims made on the label are false and/or misleading, then the product can be criticised as usual under the general misbranding and false advertising provisions of this bill.

The substitute paragraph (j) I am submitting for your approval is as follows:

SEC. 402. A drug shall be deemed to be misbranded—(j) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for use on or within the body, except as provided in (k) of this section, and its labeling fails to bear a plain and conspicuous statement of such use, including the strength or dilution, and if 5 cubic centimeters of the dilution specified is not capable of killing in vitro within 5 minutes at 37° C. not more than 0.5 cubic centimeter of a 24-hour broth culture of staphylococcus aureus which when tested in vitro at 37° C. is killed by 5 cubic centimeters of a 1 to 80 aqueous dilution of phenol, in 10 minutes but not in 5 minutes. *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of any advertised use or by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical professions, or appears only in scientific publications of these professions.

The suggested wording of paragraph (j) which I am submitting does not preclude the use of germicidal tests in which amounts of culture less than 0.5 cc are used, since the wording states specifically

"not more than 0.5 cc of culture" in 5 cc of the antiseptic being tested.

The word "duration" as it occurs in line 24 of paragraph (j) of section 402 has been deleted from the suggested rewording of this paragraph submitted herewith. This has been done because the duration of application of an antiseptic usually has very little if any relation to the duration of germicidal activity. In other words, the antiseptic does not leave the site of application as soon as the user stops applying it. When the surgeon uses tincture of iodine, for example, in preoperative skin preparation, he simply applies the antiseptic and then waits 5 minutes before starting the operation. He does not continue to apply the germicide to the skin for 5 minutes, but he allows it to act for 5 minutes after it has been applied. The same is true of the use of silver compounds in the nose. The time of application is momentary—just long enough to drop the solution into the nose—but the germicide remains on the tissue and its activity continues for hours. Even in the case of antiseptics used as throat gargles, the activity continues for an unknown and indefinite period after the solution has been expectorated. It is actually impossible to determine how long the activity of any antiseptic continues after application, hence it is unreasonable and unfair to be required to state the duration of application on the label. Such a statement would be meaningless. It is inconsistent to require by law that meaningless statements must be placed on labels of any food or drug; on the contrary efforts are and should be made to keep them off of such labels.

My objections to paragraph (k) are somewhat the same as already indicated for paragraph (j). Here again no indication is given as to what method is used for testing the bacteriostatic value of antiseptics recommended for inhibitory use. Slight variations of a single method (the agar-plate method) are being used by the Food and Drug Administration for testing such preparations. Simple mention of the agar-plate method is sufficient to give the information necessary as to the method of test intended.

The word "duration" should be deleted from line 18 of paragraph (k) of section 402 for technical reasons. It is required under the present wording of this paragraph that the antiseptic for inhibitory use must be employed for a sufficient time to inhibit the growth of bacteria, and that the product by standard test must inhibit the growth of bacteria used in the test for the duration of time specified. Since 24 hours is the shortest time the test can be done in order to obtain a reading of results, it means, according to the present wording, that all antiseptics for inhibitory use must be used for 24 hours. There are many instances in which this would be impracticable and not feasible. It is suggested that the wording of this paragraph be changed to take into account the two objections just described. I am taking the liberty of submitting such a paragraph to you for your consideration.

The substitute paragraph (k) I am submitting for your approval is as follows:

SEC. 402. A drug shall be deemed to be misbranded—

(k) If it purports to be or is represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body, and its labeling fails to bear a plain and con-

spicuous statement of such use, including strength or dilution, and when tested by a standard agar-plate method for determining inhibitory effect, it fails, in the strength of dilution prescribed, to prevent the growth of a culture of staphyococcus aureus of the resistance specified in paragraph (j) of this section. *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of any advertised use or by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical profession, or appears only in scientific publications of these professions.

The fact that I am submitting substitute wording for paragraphs (j) and (k) of section 402 does not mean that I am agreeable to including this special legislation in this bill. On the contrary, I am definitely opposed to such unfair and unwarranted discrimination. It was indicated in the beginning of this statement that antiseptics can be and are being regulated under the general provisions of the Food and Drug Act of 1906. I hardly need to tell you that the provisions of S. 5 are also sufficiently broad to cover this class of drugs. After all, antiseptics are drugs, just as laxatives, anaesthetics, and so forth, are drugs.

In section 201, paragraph (B), the term "drug" is defined as—

(2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; * * *

Antiseptics are covered in this definition of the word "drug", since they are drugs intended for use in the cure, mitigation, treatment, or prevention of disease.

There should be no misunderstanding as to the meaning of the word "antiseptic." Our standard lay and medical dictionaries are sufficiently clear as to the meaning of this term. For your information I will quote here the definition of the word "antiseptic" as it occurs in the current edition of Webster's New International Dictionary (second edition, 1934):

antiseptic, n. A substance that opposes sepsis, putrefaction, or decay; one that prevents or arrests the growth or action of microorganisms, either by inhibiting their activity or by destroying them; used especially of agents applied to living tissue. Cf. Disinfectant, germicide.

I invite your attention to the double meaning which is attributed to this word. Antiseptics prevent the growth or activity of microorganisms by either inhibiting their growth or by destroying them. In other words, antiseptics are either bacteriostatic in their activity or they are germicidal in their effect. This same definition is expressed in somewhat clearer language in the book, The Newer Knowledge of Bacteriology and Immunology, by Jordan and Falk (1928), in chapter XXII, page 307, as follows:

Antiseptics are substances which, when applied to microorganisms, will render them innocuous, either by actually killing the organisms or by preventing their growth, according to the character of the preparation or the method of application.

This is essentially the same definition given by the United States Food and Drug Administration in Department of Agriculture Circular 198. This circular, entitled "United States Food and Drug Administration Methods of Testing Antiseptics and Disinfectants", gives the following definition of the word "antiseptic" on page 10:

According to current usage the word "antiseptic" has two meanings; to kill bacteria or to prevent their growth, depending upon the use of the product.

Products such as salves, ointments, and dressings that remain in contact with the body for long periods of time, may be designated properly as antiseptics if they inhibit the growth of bacteria. On the other hand, mouth washes, douches, gargles, and preparations of like nature are in contact with the body for but brief periods of time and exert negligible inhibitory action. These may be described properly as antiseptics only if they will destroy bacteria under the conditions of use; that is, in the dilutions recommended and in a period of time comparable to that in which they would have an opportunity to act when used as directed.

It would seem from the foregoing that there is already ample authority for the definitions of the word "antiseptic" as given in paragraphs (j) and (k). It is therefore not necessary to include a definition of this word in a proposed law of this kind. There is no more need for such definition in this bill than is there need for including definitions of other classes of drugs.

Another reason why even the recommended substituted wording of paragraphs (j) and (k) really should not be included in this bill is that the methods of test outlined in them are methods which are already standard in this country. They have been accepted by the professional bacteriologists of the United States and recognized by them as the standard methods for testing antiseptics. This acceptance and approval by the profession is further supported by authors of textbooks on bacteriology. These methods are published in detail in such books as The Newer Knowledge of Bacteriology and Immunology (1928), by E. O. Jordan and I. S. Falk and in the Textbook of Bacteriology (1934), by H. Zinsser and S. Bayne-Jones. These books are recognized by bacteriologists generally as outstanding reference and textbooks in this field. In addition to acceptance by authors of bacteriology textbooks, these standard methods have been adopted as the official methods of test by the United States Food and Drug Administration.

It is evident, then, that antiseptics can be adequately controlled and regulated under the general provisions of this bill (S. 5). The definition of the word "drug" as given in this bill covers this class of drugs without any special legislative treatment whatever. The definition of the word "antiseptic" in standard current dictionaries in sufficiently clear so that no difficulty should be experienced in this regard. Our standard methods of testing antiseptics are satisfactory and applicable to use by the Food and Drug Administration for the purpose of controlling this class of drugs. There is, therefore, no necessity for any special legislation such as is included in paragraphs (j) and (k).

If, in the face of all the facts, the Committee on Commerce feels that this discriminating legislation against antiseptics as a class must be included in this bill, I would like to direct your attention to some of the pitfalls which might develop as a result of retaining paragraphs (j) and (k) of section 402 as they are now worded. In paragraph (j) of this section, two methods of test are indicated. While the word "standard" is applied to both of these tests, there is no assurance that in the future, or even at the time this proposed law should become effective, tests might not be employed by the Food and Drug Administration which had not first received the approval of professional bacteriologists generally. In other words, the officials of the Food and Drug Administration might make use of tests which seemed suitable to them, but without first making sure that the

methods employed had received the approval and recognition of the bacteriologists outside of the Department of Agriculture. In this connection I wish to submit the definition of the word "standard" as given in Webster's New International Dictionary, Second Edition, 1934:

> **Standard, n.** That which is established by authority, custom, or general consent, as a model or example; criterion; test; in general a definite level, degree, material, character, quality, or the like, viewed as that which is proper and adequate for a given purpose.

A standard method must be established by authority, custom, or general consent. It is quite possible that the officials of the Food and Drug Administration might not consider it necessary to wait until newly developed methods had become established by authority, custom, or general consent before making use of them in the regulation of antiseptics. Should this be done, the methods employed would not be "standard" and they might not be legal under the law. The Department of Agriculture might claim the right to set up its own "official" methods, but if these were new and untried procedures and had not become "established by authority, custom, or general consent" they would not be "standard" methods.

This is not an academic discussion of a remote possibility, but is actually a probable result of this indefinite language. Suppose, for example, that the officials of the Food and Drug Administration should decide that they disliked any reference to antiseptic qualities on the labels of certain classes of antiseptics. Even though our standard methods of test showed these products to be antiseptic, procedures could be developed which could show that such an antiseptic did not demonstrate the same "germicidal effect in the strength or dilution and within the duration so prescribed of a 1 to 80 dilution of phenol * * * for 10 minutes at 37 degrees centigrade" by another method. A 1 to 80 dilution of phenol actually sterilizes the culture of the test organisms used in this standard test in 10 minutes at 37 degrees centigrade. The antiseptic being tested must, according to paragraph (j), kill all microorganisms under any test which the Department of Agriculture might see fit to devise. It is quite possible to devise tests which would prevent any antiseptic from killing all the microorganisms present under the special condition of such a test. Since under these conditions the antiseptics could not accomplish the same results as resulted from 1 to 80 dilution of phenol in 10 minutes at 37 degrees centigrade by another test, then these drugs could not even be labeled as antiseptics. That is the possible result of the present wording of paragraph (j) of section 402.

You will be interested in an example of not only a possible, but a probable result of the present wording of paragraph (j). Tincture of iodine is one of our best and most effective antiseptics. It is quite generally used in the preoperative disinfection of the skin, for which purpose it has been employed successfully for a great many years. For reasons just given, the Food and Drug Administration could, by employing certain procedures, show that even this strong germicide could not by these tests accomplish the same results as 1 to 80 dilution of phenol by another simpler and more favorable test. Therefore it could not be sold as an antiseptic. It could be demonstrated by such procedures, which the Department of Agriculture might set up as "official" tests, but which would not be "standard" methods, that no antiseptic no matter how effective it might be in clinical use, could be labeled as an antiseptic.

It is not the intention of the Committee on Commerce, I am sure, to land its support to such absurd potentialities as lie in the present wording of paragraph (j) of section 402. The chaotic possibilities that are now in this paragraph could be eliminated entirely by changing the wording so that the antiseptics being regulated would be tested by the same method as used in the test applied to 1 to 80 dilution of phenol. It is not unreasonable to require that antiseptics should be equal to a 1 to 80 dilution of phenol in germicidal efficiency when tested by the same method. This is reasonable, fair, and scientific.

It is suggested that the substitute wording for paragraph (j) and paragraph (k), which has already been submitted, be used. The reason for this recommendation is that the substituted wordings are far more definite and scientific and more easily understood. In a law of this kind, as in all laws, vagueness is to be avoided. Definite wording of such clearness that all may read and understand alike is not only desirable, but absolutely necessary. The substituted wordings for paragraphs (j) and (k) suggested here accomplish this purpose completely. If any special paragraphs covering antiseptics are felt really necessary by the committee, it is strongly recommended that the substituted wordings presented here be used in place of paragraphs (j) and (k) as they now occur in section 402.

Mr. Syme.

STATEMENT OF SAMUEL A. SYME, DRIED FRUIT ASSOCIATION OF CALIFORNIA AND THE CALIFORNIA DRIED FRUIT EXPORT ASSOCIATION

Mr. SYME. Mr. Chairman, I represent the Dried Fruit Association of California and the California Dried Fruit Export Association. These organizations have in their membership individuals and organizations handling 95 percent of the dried fruit produced in the State of California. This represents 500,000 tons of dried fruit annually, coming from more than 2,000,000 tons of fresh fruit.

I might say that we heartily endorse S. 5 in its general principles, and we are in favor of it, but we feel that the committee should make a distinction between fresh foods or natural foods and the so-called "manufactured" or "processed" foods. We feel that the bill, as drawn, is drawn primarily looking toward the manufactured foods. Dried fruits are merely fruits in their natural state, which have been dehydrated, usually by the action of the sun. They are subject to the same inconstancies that fresh fruits are subject to, the same changes in sugar or acid content, caused by climatic differences, temperature differences, and they are just as little subject to a definition of quality as is a fresh fruit.

Section 303, on pages 9 and 10, provides for the definitions and standards for food, but it ends up with the provision, as it stands at present, "*Provided*, That no standard of quality shall be established for any fresh natural food."

We would suggest that that proviso be amended to read—

Provided, That no standard of quality shall be established for any fresh or dried fruits or vegetables.

Now, this morning Senator Austin was speaking of not wanting a definition in the act which would prohibit the defining of quality of maple sirup and he was afraid that the use of the term "natural foods" would prevent that, because maple sirup might be held to be a natural food, as milk is.

We feel that the dried fruit is no more subject to a standard of quality than is the fresh fruit. You might take two peaches off of the same tree, one of them will go to the market as a fresh peach, and the other one may go to the drying yard and be dried. The only difference between the two when they reach the market is that the chemical reaction of one of them has been somewhat arrested by dehydration.

Senator COPELAND. Is it your view, Mr. Syme, that in the establishment of a standard of identity provision might be made against worms, and so forth?

Mr. SYME. Yes; but we are not bothering with the standard of identity at all, sir. We are not contesting that. It is just the definition of quality. But a peach is a peach, whether it is in dried state or whether it is in a fresh state. We do not believe that it is any more possible to define, from the standpoint of quality, a dried peach than it is a fresh peach. That does not deal with the standard of identity, Senator.

That and one other section in the act is all that I care to take up at this time. If I may, I would like to file a supplemental statement.

Senator CLARK. That may be done.

Mr. SYME. On page 50, line 16, section 714 (d), (2):

A food, drug, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this act, (2) if it complies with the laws of the country to which it is intended for export.

Senator COPELAND. We put that in, you know, for your State.

Mr. SYME. Yes; I realize the discussion we had on that last year. We would just like, Senator, to have that put the other way around and to have it read: "Provided it does not violate the law of the country to which it is exported", as the present law has practically the same provision, and the decisions of the courts on the present law are built upon it, and those decisions would be, to a large extent, worthless the way the law is written.

(Statement referred to is as follows:)

BRIEF ON BEHALF OF DRIED FRUIT ASSOCIATION OF CALIFORNIA IN RE S. 5

The Dried Fruit Association of California desires to place on record the views of the association with respect to S. 5, introduced by the Honorable Royal S. Copeland and intended to supplant the present Food and Drug Act.

The Dried Fruit Association of California has in its membership individuals and organizations handling more than 95 percent of the State's total output of dried fruits and more than 90 percent of the dried fruits prepared in the United States. They handle something more than 2,000,000 tons of fresh fruits annually, which produces 500,000 tons of the fruit in its dried form. The production of this commodity represents the labors, and in many cases the sole support, of approximately 125,000 grower families on the Pacific coast.

This industry is heartily in accord with the legislative and regulatory activities of the Government, which will and do promote public welfare, protect public health, and prevent fraud in business, and they feel that the present proposed legislation is far superior to any which has been heretofore introduced, and on the whole they give to S. 5 their hearty support. They feel, however, that the bill as at present drawn does not in all instances distinguish clearly between what may be classed raw foods which are manufactured and prepared "ready to serve". Into the first classification fall fruits, vegetables, and staples purchased in their raw state and prepared in the home by the housewife. In the second classification fall those foods upon which the service of preparation is usually performed by the manufacturer, processor, fabricator, or packer. In purchasing these foods the housewife is also purchasing service which she must accept as having been properly performed and upon which she must rely. The needs and the problems of these two branches of the food industry are entirely different and legislation affecting one cannot necessarily be applied to the other.

A reading of the proposed S. 5 indicates that its philosophy is developed largely from consideration of manufactured foods. We do not believe that many of its provisions are intended to apply to dried fruits and it is entirely possible that the proviso of section 303 would exempt dried fruits from the necessity of being defined as to quality; but we believe that an amendment to this section is desirable for clarity.

At the hearings held before the subcommittee, Senator Austin of Vermont appeared on behalf of the maple-sugar and maple-sirup industries of his State with a request that this proviso be so amended as to exclude these products from its operation. Though maple sugar and maple sirup must, to some extent, be processed, he was afraid that in spite of this processing it might be called a natural food such as milk, which though it may pass through the process of pasteurization may also be classed as a natural food. While the process through which fruits pass in order to become dehydrated or "dried" no more deprives them of their natural characteristics than do the processes through which maple sap and milk are put, we feel that greater clarity is desirable on this point.

Fruits are "dried" by the simple process of removing a portion of their moisture content primarily through the natural action of the sun. The product is "dried" or dehydrated in practically all instances by the grower himself and the drying apparatus runs from the drying racks of the small grower to the more elaborate set-up of the larger operators. The result of this process is a commodity, the chemical reaction of which has been very largely but not entirely arrested. The product is then in a form fit for human consumption and very palatable in its then condition but it is not in the form in which it is usually consumed.

The product in its dried, semiperishable state is taken from the grower by the packers and thoroughly cleansed, sorted, packed, and stored to await shipment. It is to be remember that the product is still in its raw state. The same forces which attack the fruit before dehydration may attack it now. While chemical reaction has been arrested to some extent it has not been completely stopped. All the variations that are present in the fruit in its fresh form are still there. Different districts on the Pacific coast produce fruits of the same variety but of widely varying characteristics, such as sugar and acid content, skin and flesh texture, color and external skin blemish, etc. This does not mean the wholesomeness of the product is necessarily variable, but rather that on the basis of limitation of the sugar content, color, and other inherent characteristics there is a variation which does not lend itself to absolute control. Dried fruits are subject to precisely the same variations of quality as fresh fruits and for this reason we feel that they are entitled to the same treatment under the law. They are condensed, semiperishable raw food of great economy to the consumer and do not lend themselves to rigid definitions of quality any more than do the fresh fruits from which they were derived.

In canning operations as to all fruit, the canner is able to exercise wide selectivity in the purchase of his raw materials. He can specify that only no. 1 (practically perfect) fruit shall be delivered. He is in a position to determine precisely the class of merchandise in which he will operate and in most instances the fruit is handled entirely by hand, even the number of pieces going into the can being carefully controlled. In performing these functions the canner is doing precisely what the housewife does for herself when she purchases and prepares for herself the fruit in its less expensive dried form. After the grower has satisfied the demands for fresh and canned fruit the remainder of his crop is put out to dry and is marketed in its dried

form, so that some of the fruit may go to the market in its fresh form and is admittedly not subject to a definition of quality; whereas other fruits from the same orchard and the same tree goes to the market in its dried form and yet might be considered subject to a definition of quality under the act as it is at present drawn.

Probably all of us have walked into a grocery store and reached into a box of dried fruits of some kind and eaten a piece of such fruit. Let us say, for example, that it was a box of dried peaches. This peach is palatable, wholesome, and nutritious but is not in the form in which it is usually consumed. We may even purchase a pound of dried peaches and at the same time purchase a bag of fresh peaches. On our way home we may have reached into the bag of fresh peaches and eaten one of those. That is admittedly not subject to a definition of quality though it may have come from the same tree that bore the peaches which have been dried and which we are taking home for final preparation. This preparation would involve a rewashing and cooking of the fruit in our own kitchen, a preparation which would have been performed by the manufacturer had the peach been canned.

Fruits may be marketed in their fresh, dried, or canned forms. In the latter instance the food is "ready to serve" and the housewife depends upon the services which have been performed for her. In the first two forms the fruit may be consumed in its raw state or it may be cooked in some form by the housewife, in either of which case the consumer has the power of selectivity and personally performs any services required.

We feel that the act may be clarified and made more practical by amending the proviso of section 303, page 10, line 4, to read as follows:

"*Provided*, That no standard of quality shall be established for any fresh or dried fruits or vegetables."

Such a proviso will remove the possibility of the inclusion of such substances as maple sugar, maple syrup, and milk from its operation and will clearly bring into the proviso dried fruits which are no more subject to a definition of quality than is the fresh variety.

At the hearing on Saturday Dr. Harrison objected to this amendment to the proviso of section 303 on the ground that it would put dried fruits in a position where they would not be regulated at all by the Food and Drug Administration, and he cited as an example the fact that fresh fruits are at present controlled by the Bureau of Agricultural Economics. It is his contention that the regulation of canned fruits is necessary because the purchaser cannot see what is in the can. This is, of course, directly in line with the argument which we have been making, namely, that the canner has a power of selectivity and performs a service upon which the housewife must depend. He further contends that while the public can observe the quality of fresh fruits, they have not the ability to observe the quality of dried fruits. Dried fruits have been on the market and extensively used for many years. Except for the removal of a portion of their moisture content, they do not differ from the fruit in its fresh state and are just as easily judged. The exclusion of this commodity from a definition of quality does not remove it from regulation, as the Secretary still has the power to regulate by tolerance the amount of sulphur dioxide which could be used in the preservation of the product. The exclusion from the definition of quality does not exclude the products from the standard of identity. The proviso of section 303 as it stands at present does not exclude even fresh fruits from the standard of identity.

Of the 500,000 tons of dried fruit produced in California annually approximately 50 percent thereof are shipped in world trade. The export section of the present Food and Drug Act (34 Stat. 768) provides that: "No article shall be deemed misbranded or adulterated within the provisions of said sections when intended for export to any foreign country and prepared or packed according to the specifications and directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which such article is intended to be shipped."

This section has been construed and applied by the courts in many instances and in so doing the courts have held the burden of proof to rest upon the Government to prove violation of the laws of the foreign country. We feel that section 714 (d) (2) would be more in accordance with the existing law and preserve the decisions under the existing law if it were amended to read: "Does not violate the laws of the country to which it is intended for export."

At the hearing of the subcommittee on this bill Senator Copeland suggested that the present section was drafted last year at the request of this association.

We would like to suggest to the Senator that the change made in the export section of S. 2800 was the striking out of the provision that foods intended for export were required to comply with a definition of quality and standard of identity set up in accordance with the act for domestic foods. Our sole purpose in suggesting this present amendment is to preserve the existing court decisions on this point and not word the act in such a way as the burden of proof in compliance might be placed upon the shipper rather than the burden of proof in violation being placed upon the Government.

In closing we wish to express our appreciation for the work of the subcommittee in conducting these hearings and to assure the committee of our hearty cooperation in the end which they are seeking to accomplish.

Respectfully submitted.

SAMUEL A. SYME,
Representative Dried Fruit Association of California.

Senator CLARK. Mr. Cosgrove.

STATEMENT OF EDWARD B. COSGROVE, REPRESENTING THE NATIONAL CANNERS' ASSOCIATION

Mr. COSGROVE. Mr. Chairman and Senator Copeland, my name is Edward B. Cosgrove, and I am representing the National Canners' Association. The National Canners' Association has a membership of some 2,000 members, and these members pack approximately 70 percent of all the canned foods that are packed in the United States exclusive of milk. As we find the third print of S. 5, the committee print, we are in almost entire accord with it. We believe that it marks a very definite step in food legislation, and we heartily endorse it.

There is a little ambiguity in the language of section 704, concerning which we would like to file a statement during the coming week, or prior to the closing of the record.

Senator CLARK. That may be done.

Mr. COSGROVE. We should also like to file a little more complete statement of the reasons for our endorsing this bill.

If you will turn to page 43, section 711, subparagraph (c), we have one very minor amendment we would like to suggest. During the past our members have sometimes had the difficulties of obtaining samples of food which had been seized. We have been put to the necessity of hiring attorneys in order to get these samples back at different times, and we should like to add to the language in line 24 following the word "obtain" the following line "by attorney or agent at his option." That would permit a canner in case of seizure to obtain possession of his own goods. Other than that, sir, we heartily endorse S. 5 and urge its speedy passage.

(Statement referred to is as follows:)

SUPPLEMENTAL STATEMENT ON S. 5 SUBMITTED BY E. B. COSGRAVE, CHAIRMAN OF THE LEGISLATIVE COMMITTEE, NATIONAL CANNERS ASSOCIATION

The National Canners Association includes in its membership individuals and firms that produce a large proportion of the output of the 2,500 concerns engaged in the canning business. It is fully representative of the industry on the basis of both character of product and geographical distribution of establishments.

The National Canners Association endorses the revision of the Food and Drugs Act as proposed in committee print no. 3 of S. 5, first, because it will strengthen the food laws. Since the passage of the original act in 1906 the

association and the industry it represents have, as attested by officials entrusted with its administration, cooperated in the enforcement of the law. Moreover, the industry has not only consistently opposed amendments that would weaken the act, but has also actively sought and assisted in securing amendments that would strengthen it.

Second, the association approves the bill under consideration because it would continue in force the provisions of the McNary-Mapes amendment to the Food and Drugs Act. This amendment was sponsored by the canning industry as a measure that would strengthen the food laws by requiring substandard canned foods to be labeled as such. Experience of both food-law officials and the canning industry under this amendment, it was believed would furnish a sound basis for further development of labeling requirements and procedure.

Third, the association approves the bill because it does not incorporate grade-labeling requirements. The great majority of the canning industry is definitely opposed to grade-labeling plans as referred to by several witnesses who appeared at the hearing, because such plans are both unenforceable and of questionable value to the consumer. The industry is just as definitely desirous of improved labeling, as sound basis for which is the continuance of the McNary-Mapes provisions of the food law and the development of a system of description labeling for those products which meet or are above the McNary-Mapes standard. The bill in the form now before the subcommittee leaves the way open to the canning industry to work out in cooperation with food-law officials methods by which labeling may be improved for the benefit of the consumer and with assurance of enforcement.

The revision of the Food and Drugs Act as proposed in committee print no. 3 of S. 5 is, in general, satisfactory from the canning industry's point of view. The industry recognizes the many difficulties encountered in formulating a bill that will accomplish the desired purposes without at the same time imposing some degree of hardship upon the industries affected. Accordingly, this industry has sought only such changes in the original measure as would clarify its provisions, improve where possible the procedure in its administration, and modify requirements that would be burdensome to the industry without commensurate benefit or protection to the public.

One further change is desired, as was outlined in my oral statement at the hearing on March 8. This is the insertion in subparagraph (c), section 711, of language which would enable a canner, in case of seizure of his product, to obtain possession of representative samples by either agent or attorney, without the necessity in all cases of employing an attorney. This change was also suggested by Mr. Charles Wesley Dunn in this appearance before the subcommittee.

The association not only endorses the revision of the Food and Drugs Act as proposed, but urges an early report upon the bill and its speedy passage.

I thank you.

Senator CLARK. Mr. Bigelow.

STATEMENT OF HORACE W. BIGELOW, GENERAL COUNSEL AND CHAIRMAN OF THE COMMITTEE ON LEGISLATION FOR THE AMERICAN DRUG MANUFACTURERS' ASSOCIATION

Mr. BIGELOW. Mr. Chairman and Senator Copeland, my name is Horace W. Bigelow; I am general counsel and chairman of the Committee on Legislation for the American Drug Manufacturers' Association. That association is composed of those manufacturers of medicinal products which are used by druggists in compounding physicians' prescriptions, and also by physicians who dispense direct to their patients.

At the beginning of these hearings, the first witness, Mr. Charles Wesley Dunn, made the statement that he represented the American Pharmaceutical Manufacturers' Association, who are the manufacturers of medicinal products for use on physicians' prescriptions. It is true that the American Pharmaceutical Manufacturers' Association is composed of manufacturers who manufacture such products.

On the other hand, my association is composed of manufacturers of the same type, and included in its membership are some of the largest manufacturers of that type in the country, who have not only a nationwide, but an international distribution of their products. I refer to such firms as Eli Lilly & Co., E. R. Squibb & Son, Parke, Davis & Co., Sharpe & Dome, Inc., and many others.

I make this statement without any intention to disparage Mr. Dunn's association or Mr. Dunn personally, but for the purpose of clarifying the record so it will not appear that all pharmaceutical manufacturers of this type are in complete accord with Mr. Dunn's views and in his endorsement of this bill.

Our association has always been mindful of the fact and in complete accord and in full sympathy with the proposition that the safeguarding of the public health is paramount to any commercial interest. Consequently, we are in full sympathy with the underlying principles and purposes of this measure. However, we are not in complete accord with the view that these purposes can best be accomplished by a complete rewriting of the act. We have entertained the hope for some time that the present law might be amended to accomplish those purposes without entirely repealing it.

I am reminded of a house that I lived in when I was in school. It had a very fine stone foundation and stone walls that went up to the second story. After I left school that house had become about 25 or 30 years old, and it became necessary to either tear it down or remodel it. It was remodeled and these stone walls and the foundation were maintained. And when I returned several years later here was a house that appeared the same to me on the outside as it did when I left school. It had the same solid foundation that it had before, but the contour had been somewhat changed. My point is that I believe that the present act furnishes a foundation upon which can be built amendments which will serve the purpose which everybody is striving for in connection with this legislation.

Also on that point I feel very strongly that the repeal of the act will do away with the many interpretative decisions that have been handed down by the courts. It will also handicap those manufacturers who have Nation-wide distribution of their products in the various States wherein the acts of these States have been built up and simulate the present Food and Drugs Act. I think this is very important and ought to have the consideration of the committee.

Senator COPELAND. May I say, Mr. Bigelow, for myself, it has had serious consideration.

Mr. BIGELOW. I know that, Senator Copeland. I am expressing the views of my people. I am not going to, today, attempt to cover a number of objections or suggestions we have in connection with this bill, but I do want to address myself to one of the things that is of most vital importance to our group, and that is the so-called "variation clause", which is found in section 401, paragraph (b).

Senator COPELAND. This witness is also a candidate for the medal.

Mr. BIGELOW. I do not get what medal you are talking about.

Senator COPELAND. I said anybody who could write that paragraph deserved a medal.

Mr. BIGELOW. I am going to try for the medal, Senator. I have something to offer in a moment. [Laughter.]

I want to, before going into this discussion, read a statement that was made by Mr. Frank G. Ryan in 1914 when president of my association. I think Mr. Ryan has stated the purpose and the intent of this variation clause better than I could put it in my own language, so if you will bear with me I will read it.

In 1914 Mr. Ryan said:

During the past year indications have appeared that an attempt will be made to amend the pure food and drugs law with a view of doing away with the so-called "variation clause." To those who have not given careful study to this subject the suggestion may seem desirable; but when carefully examined it will be found that its effect will be very far-reaching, and in fact will prohibit the sale of large classes of medicinal products, such as the mother tinctures of the homeopathis physician and specific tinctures of the eclectics, and any improved pharmaceutical or chemical product not conforming to the standards of the Pharmacopœia or National Formulary, thus stifling all progress in the manufacture of medicinal substances until such time as those in authority may see fit to recognize such improvements. With the few exceptions where the public are purchasers direct, pharmaceutical products are sold through the drug trade, or used by physicians who certainly should be able to read labels and decide for themselves what product is wanted, and a definite statement of the exact strength of a product distinctly on the label should be all that should be required.

The following year Dr. J. H. Beal—that is in the year 1915—made these points in an address to the American Pharmaceutical Association:

1. The Pharmacopœia is a book of limited standards properly applicable to drugs and chemical products only when used in pharmacy and medicine.
2. The variation clause is essential to the utilization of certain natural products in a perfectly proper and legitimate manner.
3. The restriction of medicaments to one particular standard which could not be varied from under any circumstances, would be an unwarranted interference with the freedom of choice of medical practitioners who might prefer a different standard.
4. The insistence upon an invariable standard which under no circumstances could be departed from requires the unwarranted assumption that the present official standards are perfect standards, and would operate to delay the introduction and use of improved and superior therapeutic products.

Those statements were made in 1914 and 1915.

With respect to the variation clause as we find it in the bill that is before us I asked Mr. Charles J. Lynn, vice president of Eli Lilly & Co. to examine this clause and let me have his comments. I did this because Mr. Lynn helped draft the act of 1906, and perhaps knows more about it from our viewpoint than any other man in our industry. I want to read the telegram which I received from him. It reads:

The variation clause or provision in S. 5, print 3 is not satisfactory in that it requires the manufacturer of the original product appropriated by the revision committee for inclusion in the United States Pharmacopoeia or National Formulary to state on his label wherein his products differs from the official product in those cases where the revision committee has modified the manufacturers original formula. It provides further that this difference must be shown in juxtaposition which is a physical impossibility in the case of many small labels. It ought to be sufficient where the formula differs that the manufacturer clearly state on the label of his product its own standard of strength quality or purity as provided in the present law. In considering this question of the language of the variation clause it must be kept in mind how these products get into the United States Pharmacopoeia or National Formulary. It must be remembered that the revision committees originate nothing but simply take that which has been introduced by some manufacturers and usually with certain changes in title or formula although sometimes

without change for inclusion in the official compendiums. It is inconceivable that Congress would fail to recognize the property rights of the manufacturer under these circumstances and force him to so label his original product as to convey the idea that because of an admitted difference in formula his original product was somehow inferior. That is the impression such unjust label provision would give the average buyer.

Mr. Lynn supplemented that telegram with a letter in which he said:

Regarding any change in the wording of the present variation clause in the Federal Food and Drugs Act, I want to call your attention, by way of two illustrations, only to what would happen to a manufacturer should the variation clause as now appearing in the Copeland bill be adopted.

We offered to the medical profession the original Ephedrine inhalant on which we were granted United States patents. For a time we issued licenses to other manufacturers under those patents but decided finally to surrender our rights and dedicate our patents to the public. This dedication is a matter of record in the United States Patent Office.

Our formula for Inhalant Ephedrine Compound is as follows—I won't read the formula, but merely state that the formula is stated, and I will go on and read the rest of it and then I will explain it.

It has come to our attention, through a national formulary bulletin, that a subcommittee recommends the inclusion in the National Formulary of a compound ephedrine spray of the following formula. The second formula differs from the first one, which I have not read, and I won't take the time to read that.

While the National Formulary calls the product a "spray" rather than an "inhalant" no doubt "inhalant" will be included as one of the synonyms.

If the recommendation of this subcommittee is followed and if the variation clause as now provided in the so-called "Copeland bill" is adopted, it would become necessary for Eli Lilly & Co., the original maker of this product, to put a statement on its label showing wherein its product differed from that of the National Formulary because if you will compare the two formulas you will note a difference.

Surely no one will claim that such a requirement of law is fair. Any statement on the label which emphasizes the fact that there is a difference in the formula offered by the manufacturer and that of the United States Pharmacopoeia or National Formulary is bound to create a doubt in the mind of the buyer as to the worth-whileness of the maufacturer's product. In the eyes of many, the official standard means perfection while any departure therefrom creates suspicion and doubt as to the reason therefor.

It should be sufficient, as provided in the present variation clause for a product, where it differs from one in the United States Pharmacopoeia or National Formulary, to carry a simple but clear statement as to its own standard of strength or purity.

We were the first, likewise, to offer an ephedrine jelly to the medical profession under the following formula—and I won't read that because the same situation applies there.

Now, subcommittee no. 7 of the revision committee of the National Formulary recommends for inclusion in the National Formulary an ephedrine jelly under that title of the following formula—and I will not read that formula.

Again I ask, is it reasonable when the revision committee of the National Formulary adopt a manufacturer's product for inclusion in the National Formulary but with some modification as to formula, that the manufacturer should be forced to add a statement to his label stating wherein his product differs from that of the National Formulary? I ask further, is it just?

The variation clause as it appears in the present act or as it appears in the Mead bill, H. R. 3972, is the way it should stand in the final draft. Dr. Wiley, who sponsored the present variation clause as I recall, knew what he was about.

When one realizes that the revision committees of the United States Pharmacopoeia and the National Formulary originate nothing but in every instance appropriate the work of some outstanding manufacturer with such modifications as they wish to adopt, one must realize that the manufacturer's property right is entitled to prime consideration. This definitely calls for a variation clause such as we have in the present act and no other excepting to provide for such additional language as will take care of the matter of identity.

I now get down to the amendment which I wish to suggest.

Senator COPELAND. You heard Dr. Woodward and Dr. Little and then the other day Dr. Fischelis all propose to take out the language on lines 10 to 18, inclusive?

Mr. BIGELOW. I might say on that in connection with Dr. Fischelis' statement that Dr. Beal, whom you know very well, Senator, and who has discussed this matter with you, personally disagrees with Dr. Fischelis. Dr. Beal is chairman of the board of trustees of the U. S. P. convention. He is also member of the board of directors or board of control of the association which Dr. Fischelis represents. There seems to be some conflict of opinion between Dr. Beal and Dr. Fischelis as to the necessity for a variation clause.

As to Dr. Woodward's statement, I disagree with it, naturally.

Senator COPELAND. You are going to offer new language?

Mr. BIGELOW. I am; yes, sir.

Senator COPELAND. Now, let me ask you, with no desire to hurry you, would it not be just as well if you would let us have that language so that we could see it?

Mr. BIGELOW. I can give it to you as soon as it has been read.

Senator COPELAND. Would you not have it typed?

Mr. BIGELOW. I have it typed now, Senator.

Senator COPELAND. Then we can read it all right.

Mr. BIGELOW. I can put this in the record if you want me to.

Senator COPELAND. If you can do that, because it is so complicated, and I would not want my chairman here to get excited over this scientific stuff, which is a little bit out of his line, although his knowledge is very broad.

The CHAIRMAN. The Chair said this morning that it was the purpose to hear all these witnesses today so that this bill could be reported on.

Mr. BIGELOW. Do you want it at this time?

Senator COPELAND. No; it is not necessary just now.

Mr. BIGELOW. For the purpose of the record perhaps I had better state the changes.

In section 401, paragraph (b), page 13 on line 23 after the next to the last word on the line insert the word "identity", and a comma.

On page 14, line 11, strike out the last two words.

Senator COPELAND. Does all this bring it in harmony with the letter Dr. Beal wrote me, and which I showed you?

Mr. BIGELOW. No. I will state very frankly that what this amendment accomplishes between lines 10 and 18 on page 14 is a rewriting of those few lines so it brings the variation clause in line with the variation clause in the present act. That is the purpose of it.

On page 14, line 11, strike out the last two words.

On line 12 strike out the first two words, and insert in lieu thereof the word "if."

In line 12 make the word "standards" singular, and after the last comma in the same line insert the word "identity."

Strike out all of line 13 except the last two words, and insert in lieu thereof the words "be plainly stated on."

Strike out all of lines 14 and 15 and insert in lieu thereof the words "although the standard may differ from that."

Strike out the first and last words of line 16.

Strike out all of line 17.

In line 18 strike out the word "such" and insert the words "an official."

Now, these are suggestions for amendment to this particular clause.

I want to refer to two other paragraphs. As to paragraph (b) of section 401 on page 15 that has already been commented on, and there is some question in our minds and apparently in the minds of several others as to whether or not this does not invalidate the variation clause. For that reason we ask that this be stricken out. We also ask that it be stricken out for the reason that we cannot determine it will serve any good purpose.

Senator COPELAND. Your position is the same as Mr. Craig's in that matter?

Mr. BIGELOW. I did not hear what Mr. Craig had to say about it.

In paragraph (g), page 17, we would like to have lines 18, 19, and line 21 and up to and including the period after the word "therein" stricken out. That is the paragraph with respect to the packaging and so on in accordance with the provisions of the Pharmacopoeia and the National Formulary. I think in some of our discussions, Senator Copeland, I brought out the point that the Pharmacopoeia and the National Formulary are books of standards for the retail druggists. And to apply the restrictions as to packaging and so on to a manufacturer on a commercial scale is an impractical proposition. For instance, take cinnamon bark. It says in the Pharmacopoeia, "Preserve in tightly closed containers." We receive it in bags or bales.

As to chloroform the United States Pharmacopoeia says:

> Preserve in well-stoppered bottles, in a cool place, protected from light. Protect chloroform from contact with cork stoppers by covering them with tinfoil or other suitable material. Sold commercially in tins and ampoules.

Digitalis is somewhat in the same classification as cinnamon bark. The United States Pharmacopoeia says:

> Preserve in airtight containers. Sold commercially in large bales. Kept in lofts.

And another one is solution ferric chloride, the United States Pharmacopoeia says:

> Preserve in glass-stoppered bottles, protected from light. Sold commercially in steel drums in bulk. Also sold at retail in cork-stoppered flint bottles.

There are several other examples that I might cite. In addition to that objection there has been some question raised as to whether or not this language might also invalidate the variation clause. I do not see myself what is to be accomplished by it.

As to paragraphs (j) and (k) in section 402, these are the so-called "antiseptic and germicide clauses." All I want to say about that is the same thing I have said to you on a number of occasions, Senator Copeland, and that is that we believe that these paragraphs should not be in the bill, and that the regulation of bactericides, germicides, and antiseptics should be left under the general provisions of the bill with respect to adulteration and misbranding. That has been our position. We feel that you are fixing standards, invariable standards, in this law that may retard progress.

I have some other comments which I would like to have permission to file.

Senator CLARK. They may be filed.

Mr. BIGELOW. I want to say also that Dr. Anderson of E. R. Squibb & Son has filed a statement and suggested some amendments with which our association is in accord.

Here is my suggested amendment of section 401, paragraph (b):

If its name is recognized in an official compendium, or if it purports to be a drug the name of which is so recognized, and it differs from the standard of strength, quality, identity, or purity as determined by the tests or methods of assay set forth therein; except that whenever tests or methods of assay have not been prescribed therein, or such tests or methods of assay as are prescribed are insufficient, for determining whether or not such drug complies with such standard, the Secretary is hereby authorized to bring such fact to the attention of the appropriate body charged with the revision of such compendium and if such body fails within a reasonable time to prescribe tests or methods of assay which are sufficient, then the Secretary may prescribe for the purposes of this act such tests or methods of assay by regulations as provided by sections 701 and 703. No drug shall be deemed to be adulterated under this paragraph if the standard of strength, quality, identity, or purity be plainly stated on its label although the standard may differ from that as determined by the tests or methods of assay set forth in an official compendium. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

STATEMENT OF MISS ALICE L. EDWARDS, EXECUTIVE SECRETARY OF THE AMERICAN HOME ECONOMICS ASSOCIATION

Miss EDWARDS. Mr. Chairman and Senator Copeland, my name is Alice L. Edwards, executive secretary of the American Home Economics Association.

When the representatives of the 11 national organization appeared before your committee last Saturday, they expressed the earnest desire that S. 5 (Committee Print No. 3) with certain amendments as presented by Mrs. Harris T. Baldwin be speedily enacted by Congress.

As we have sat and listened to the testimony presented at this meeting we have been appalled as we have thought of the penalty society would have to pay should the recommendations of some of the witnesses be incorporated in this food, drugs, and cosmetic bill and be enacted by Congress.

We have noted with grave concern the efforts which are being made to weaken the enforcement provisions of the bill. We well realize we never can have the promised protection unless the enforcement provisions of the bill have teeth in them. It would appear that opposition has been directed against multiple seizures because this

has proven the most effective weapon in the present law. We, therefore, protest against the consideration of proposed amendments which would hamper and even preclude enforcement.

The consumer organizations for which I speak insist that this bill provide proper standards for foods, drugs, and cosmetics.

We asked for multiple standards for food products. This bill makes no provision for them.

We have also protested against the striking out of that line in section 401 (b), line 22, on page 13, which provides that a drug shall be adulterated if its name is recognized in an official compendium and it fails to meet the definition and description set forth therein.

Senator COPELAND. What page was that, Miss Edwards?

Miss EDWARDS. That is page 13, line 22. We find in the United States Pharmacopoeia relatively brief statements about the drugs listed. These usually include several sections, the first of which usually gives the definition and description, then followed by tests for identity and perhaps those concerning purity, assay, and other items. I understand for positive identification it is absolutely necessary in the case of many drugs that they conform in all respects to the definition and description. It is perfectly possible to have two substances quite different in their physiological effects which, nevertheless, so far as the tests and methods of assay prescribed in the United States Pharmacopoeia are concerned seem identical. Compliance with the full requirements of the Pharmacopoeia, not just the tests and methods of assay, is required to identify adequately these drugs.

It is only fair that any manufacturer who wishes to profit by the prestige given by the recognition of a drug in the Pharmacopoeia should be required to maintain in his product the standards set up for that product, the only variation to be permitted being in the strength of crude drugs used for the manufacture of finished products which comply with the United States Pharmacopoeia. If he wishes to manufacture a product varying from this standard he should be required to choose a name for it which definitely differs and differentiates it from the Pharmacopoeia product.

If a product is sold under the Pharmacopoeia name it should be composed of the substances it is supposed to contain; it should be made of products from the source designated. Otherwise it may not have the expected physiological effect.

It is no conciliation to an orphaned child to be assured that the ineffective drugs administered to his mother met the required chemical tests.

To require only partial conformity to Pharmacopoeia standards is to legalize a form of misbranding.

We have asked for the listing of ingredients on the label of all foods, drugs, and cosmetics. We believe we are perfectly justified in asking that these be given in the order of their predominance by weight. But if this order is not to be required we insist that at least the ingredients be given. It is essential in order that an individual may avoid products containing substances for which he or she may have an allergy. In other words, from recent developments in medical science we know the health of many persons is dependent upon their being able to obtain this information and avoid substances

which are deleterious to them, although perfectly satisfactory for most other people to use.

Although we have voiced approval of S. 5, Committee Print No. 3, with the few amendments listed by Mrs. Baldwin, we wish to repeat that this bill represents a compromise. We are unwilling as consumers to make further concessions.

With each passing month women in our organizations are becoming more intelligently critical of the provisions in the bill, and will insist upon more protection, not less, as the passage of the bill is delayed. We have urged prompt action on this bill for we are not unmindful of the fact that continued delay is an economic injustice to consumers, and to some spells blindness, physical injury, or even death as menacing products continue on the market. We cannot, with peace of mind, brook unnecessary delay in the enactment of a bill to safeguard consumers of foods, drugs, and cosmetics.

May I later, Mr. Senator, file a bill of particulars stating the position of the 11 organizations regarding the amendments which have been proposed to this bill?

Senator CLARK. That will be allowed.

(Statement referred to is as follows:)

STATEMENT ON POSITION CONCERNING S. 5 (COMMITTEE PRINT 3) AND PROPOSED AMENDMENTS THERETO

We wish to reiterate our statement of support of S. 5, committee print 3, and of desired amendments which Mrs. Harris T. Baldwin presented in her testimony on Saturday, March 2. Those which we consider of greatest importance are:

1. Retention of the original provision (h) in section 3 requiring that an identification of quality be placed on the labels of standard foods instead of the new paragraph (h).
2. Listing ingredients on the labels of foods and drugs, and for drugs the specifying of quantity or proportion of each active ingredient.
3. Addition of a provision requiring the listing of ingredients of cosmetics.
4. Amendment of section 303 to provide for the establishment of multiple quality standards for foods.
5. Amendment of section 401 (b) concerning the requirements for drugs listed in an official compendium by the restoration of line 22 which reads "(1) fails to meet the definition and description set forth therein."
6. Amendment of section 501 (a) concerning deleterious substances in cosmetics by restoration of the words "the user" for which "health" has been substituted.
7. Restoration of paragraph (h) of section 501 and section 503 concerning poisonous or deleterious substances in cosmetics.
8. Amendment of section 714, paragraph 4 so as to forbid the exportation of adulterated foods, drugs, and cosmetics.

However, during these hearings various amendments have been offered, certain of which if incorporated in this bill would, in our opinion, seriously weaken it and render it wholly inadequate for consumer protection.

1. We oppose a transfer of the enforcement of the advertising provision of the bill from the Food and Drug Administration to the Federal Trade Commission.
2. We oppose any further restriction of the provisions for multiple seizures.
3. We oppose a limitation of seizures to those approved by the court.
4. We oppose the proposed requirement that at least one seizure be made in the district where the product originated or the nearest possible district thereto.
5. We oppose any transfer of items in the definition of adulterated to the definition of misbranded foods, drugs, and cosmetics.
6. We oppose exemption of the requirement that the weight or the volume of cosmetics be shown on label.

7. We oppose the omission of lines 12, 14, 15 of section 601 (6) providing for the addition of diseases to the list of those for which drugs may not be advertised to the public.

We are opposed to any further amendments which would lessen consumer protection.

Mrs. Alvin Barber, American Association of University Women; Mary A. Cindsley, American Dietetic Association; Harriet R. Howe, American Home Economics Association; Susan C. Francis, American Nurses Association; Margaret C. Maule, Girls Friendly Society of the U. S. A.; (Dr.) Lauretta E. Kress, Medical Women's National Association; Elizabeth Eastman, National Board of the Y. W. C. A. of the U. S. A.; Mary T. Bannerman, National Congress of Parents and Teachers; Louise G. Baldwin (Mrs. H. T.), National League of Women Voters; Elizabeth Christman, National Women's Trade Union League; (Dr.) Julia M. Green, Women's Homeopathic Medical Fraternity.

Miss Wall.

STATEMENT OF MISS FLORENCE E. WALL, NEW YORK, N. Y.

Miss WALL. Mr. Chairman and Senator Copeland, my name is Florence E. Wall. I am a consulting chemist with 21 years' general experience, the last 10 years of which have been devoted to educational work, research, technical development, and publicity in the cosmetic industry and its practical application in beauty culture.

I have asked the privilege of appearing before you in order to express my broad approval of S. 5 insofar as it concerns cosmetics.

To save time I wish to limit my remarks to the sections that refer to cosmetics.

Speaking unofficially, of course, and objectively, it is my opinion that the cosmetic industry as a whole could worry along very well with the provisions as they now stand. But I wish to offer a few suggestions that would not weaken the bill and which will assure us the provisions will be made more specific.

On page 2, line 13, since the early days of S. 1944, I have been suggesting that this clause about "all substances, preparations, and devices other than food, intended to affect the structure or any function of the body" is redundant. It has been already covered. If remedial claims are made they come under drug devices, and if the word "devices" is put into the definition of cosmetics, below, we shall have all these strange things accounted for that have been dubious before. All such apparatus as irons, scissors, nail files, and other things used in the beauty industry you have never had to consider before, and as you have them specified, those things are drugs.

Mr. COPELAND. Could that all be omitted?

Miss WALL. That whole thing could be omitted, provided you put "devices" in the definition of a cosmetic below, Senator. I have checked it up and it seems to square very scientifically in every way with the kind of definition you need. I do not want to split hairs or go in for facetious comments on that. Many have been made.

I still say it seems silly to have to go to the Department of Agriculture for information about lipsticks, manicure preparations, and permanent-wave machines. Surely you do not want to promulgate the idea that you think a permanent-waving machine, manicure scissors, razors, and the nose shapers that we discussed before

are drugs. Last year when we discussed that the comment was that those of us who were considered uninitiated did not realize the importance of that. I respectfully submit that I not only understand it from the drug standpoint, but I also understand it—and I have an advantage over most people—from the cosmetic and beauty-culture standpoint.

Senator COPELAND. Miss Wall, I was not clear as to what you suggested putting in there.

Miss WALL. In subsection (c) have it read:

The term "cosmetic" includes all substances, preparations, and devices.

Senator COPELAND. Yes.

Miss WALL. That covers any cosmetic device for which a claim might be made, many things that might have been considered previously as coming under (b) (3). You can avoid all equivocal interpretation by omitting (b) (3), because your drug devices, all those remedial belts and other things we discussed before are already covered in (b) (2).

Here is another thought on which I would not insist, but I think it would clarify the definitions a bit if under drugs up above there in line 11 the words are added "intended for internal or external use." I wanted to say something about the definition of a drug also that would clarify the definition. Now that you are considering cosmetics you raise a point that you have never had to consider before, that a drug which is intended for a remedial effect of some kind should be specified as for either external or internal use.

Senator COPELAND. You are speaking now about page 15?

Miss WALL. No, Senator; it is in the definition of a drug on page 2.

Senator COPELAND. Oh, the definition.

Miss WALL. So it will read:

Substances, preparations, and devices intended for internal or external use—

Anything that makes curative or remedial claims; and that would cover such cosmetics perhaps as an acne cream. Or in the cosmetics if it is specified for external use only, then it refers only to substances that are used for embellishment, and it would make that distinction very clear. To describe the cosmetic I do not think there would ever be an occasion for strange interpretation if you did it in that way. Specifying that external use for embellishment in defining cosmetics would let you catch a number of these elusive ones perhaps such as the deodorants, the mouth washes, the aromatic materials, perfumes, and such things that have been on the border line before, and have generally escaped altogether.

These subsections in the definitions, if amended as suggested, would read:

(b) (2) All substances, preparations, and devices intended for internal or external use in the cure, mitigation, treatment, or prevention of diseases in man or other animals.

(c) The term "cosmetic" includes all substances, preparations, and devices intended for external use in cleansing, or altering the appearance of, or promoting the attractiveness of the person.

On page 20 in section 501 we are glad that at least some change was made in that definition, because I feel that now the present wording views the cosmetic industry more fairly and squarely with

the other two. [This refers to the definition of an adulterated drug.]

In last year's controversy the Administration admitted that their requirements for cosmetics were more stringent than the others because they knew less about them, and they had to feel their way. Again speaking unofficially, I believe I could assure you that all the better forces within the industry would be with you in the support of such wording as this, and they will be grateful for this change.

However, I wish also to request reasonable allowance for allergy. I do not make any recommendation as to how that is to be done here in the law or in your report, but do let it be covered. It is coming up in both drugs and cosmetics, and even in foods as one of the most important things that we have to consider nowadays principally due, as I have said before, to the increasing use of coal-tar derivatives about which we do not know so much. Everybody who is using them is learning about them. It has just been called to my attention that section (e) on page 21 about the coal-tar colors raises a question that has never come up before because there has never been any regulation whatever about the pigments used in cosmetics. There are a number of colors certified for use in foods, which can be checked fairly well, because if they are taken internally it is easy enough to find out what the effect is. Many of these certified food colors are useless for cosmetics; on the other hand, many of the best cosmetic colors would be quite unsuitable for foods.

Senator COPELAND. Do you remember Mr. Craig suggested we ought to add the coloring process or something like that?

Miss WALL. I did not hear that, Senator.

Senator COPELAND. What is your attitude now on this subsection (e)?

Miss WALL. It seems this is going to bring in a vast amount of work, because there are so many pigments that can be used in powders and for variation in shades and everything.

Senator COPELAND. This relates only to coal-tar colors.

Miss WALL. Coal-tar colors; yes, sir; but that is what they have, and how could you test them. I think more study should be given to that. Possibly it should be omitted.

In referring again to the question of allergy, I do not want to waste time in post mortems, but I do wish to say briefly that most of the zeal of the professional crusaders has been based upon lack of proper perspective and balance in their interpretation of published scientific information, and through confounding the pure science, the pharmacology of a drug or chemical substance with its perfectly legitimate use in pharmaceutical and cosmetic application. By which, I mean that from their point of view they find the subject looks like this: A certain product contains phenolphthalein, caustic potash, phenol, or something of that sort, and it sounds formidable, so they look it up in some pharmacology textbook, and read all about the dreadful things that happen when large quantities of that substance are injected into a test animal or otherwise consumed. Therefore, because a certain pharmaceutical or cosmetic product is found to contain some small percentage of that they condemn it. Again, I say that is due to misinterpretation and to confusing pure science with application, and that is something we should look out for.

It will be taken care of if you give proper consideration to allergy. We all know to what silly and hysterical extremes such reasoning can lead.

In support of my contention I wish only to remind you that cosmetics have jumped from approximately nowhere in 1906 to a very high position on the Nations list of industries, and that this has been done without the benefit of legislation. So that now when you do wish to control this you have this vast industry which has come up by itself. This ought to convince us all that cosmetic products cannot possibly be so generally harmful as the crusaders would like us to believe. The occasional case of trouble is undeniably regrettable for everybody concerned, but its comparative rarity must be acknowledged, else why does such a case usually break into the headlines? I would be the last to condone the unfortunate and tragic results reported from the use of a few cosmetic products that have come in for so much notoriety the past few years, but the principal cause for regret is that there was no law and no means under the present law to protect the innocent users from such products while they lasted. My own experience has been very broad, because when I wanted to find out about this industry I went into it and worked through every phase of it with my hands, and I repeat in all good faith that the most harmful thing about most of the cosmetics produced nowadays is not the ingredients the manufacturers put into them but what they say about them in their silly advertising. Your proposed regulation of advertising seems fair enough to me. Perhaps this will insure more orders given in writing and approval of changes in copy, so that responsibility for violation can be better fixed. We discussed that in connection with S. 2800 also.

I feel we ought to have a section granting the power to exact informative labeling. You have not asked for it, but we are willing to give it to you. Of course, there would be a reluctance. If everybody had to do this, everybody would do it. But while there is nothing to demand that, of course, there is now reluctance on the part of some persons to expose themselves to the consequences of informative labeling, but if it were required everybody would do it. By this I do not mean a declaration of ingredients, which usually does not mean a thing; but protective notices, which will admit the presence of an allergic substance and warn the user accordingly. Then we would regulate all these substances so that could be taken care of as we take care of them now under the sanitary code for the municipal regulations in New York City. On page 27 the specifications that the distinguished scientists on the board of public health be distinguished for their attainments and interests in these industries, that at least assures us that the personnel will not consist entirely of physicians. I work with the physicians, and I have many good friends among them, but I have no illusions about them. Few of them could possibly claim to be scientists in the true sense of the word, because is it not generally admitted that the practice of medicine is an art?

Senator COPELAND. I admit it.

Miss WALL. There has been a quaint notion afloat that physicians are the only ones qualified for public-health work, yet public-health work demands a good, thorough knowledge of many branches of

science, biology, pharmacology, chemistry, bacteriology, dietetics, and even physical education. So we are grateful for this, and we hope that that will be left.

I think the high spot in this is the proposed appointment of advisory committees from the industries themselves. We can hardly ask for more than that, because it practically puts it up to each industry to formulate the rules for its own regulations. It was the lack of such provision that was the principal point of all my objections to these bills before. In the 10 years in which I have been working in this industry I have never opposed Government regulation of cosmetics. I was like many persons who stumble upon cosmetics, professional people, and particularly physicians, who wonder why it has not been controlled, and how this industry has been rising as it has since 1906 without any control. So I say now that you have this I want to support it. As long as it seemed that hte cosmetic industry was to be controlled from the outside by regulations formulated by agrarian economists and lawyers, and their professional reformer friends, I had to be consistent and I could only conscientiously oppose it. I still feel the control of cosmetics and drugs belongs more appropriately in the National Institute of Health than in the Department of Agriculture, but if it must be in the Department of Agriculture then I say that what the cosmetic industry needs to do now is to assemble the strongest possible representative committee and work right along with them now that it has the chance.

The inference has frequently been made by the professional reformers that cosmetic manufacturers have been enjoying a field day in their lack of Government control, and that they, therefore, oppose legislation. The facts should give ample evidence to the contrary. Throughout all the voluminous records of the hearings on these various bills, it is significant that no representative of the cosmetic industry, official or unofficial, has protested the idea of legislation itself; and that all criticism of these proposed bills has been entirely constructive.

The legitimate manufacturers will not suffer under this bill if it should be made law, not because Senator Copeland is secretly in league with them in their nefarious enterprises, as the crusaders would have us believe, but because the provisions of this bill, on adulteration, misbranding, and enforcement, will protect them against the activities of the bootleggers, and petty imitators who will be caught either directly by this Federal law or by the avalanche of State laws which must soon follow its enactment.

So it can hardly be alleged that the cosmetic industry fears Government control because of any guilty conscience as to what they use in their aids to beauty. Aside from a few fetiches, taken over bodily from medical publications, even the reformers now seem to be concentrating on the advertising. It would seem that the field day has been celebrated rather in this side of the camp. In blasting their ridiculous effusions to nothing, I actually agree with the professional reformers, but here, too, I have the advantage of inside knowledge, because instead of staying away from the advertising people in antiseptic aloofness, I used to stand right up as one of their number and tell them that they had all this coming to them.

I said last year that I was for 7 years an active member of an organized advertising group, so I know something about the makings

of advertising and its makers. Theoretically and collectively, organized advertising approves reform, preaches reform and "truth in advertising", and thinks it practices them; but practically and individually, its members feel full of personal righteousness and seem to be suffering from near-sighted mental astigmatism.

Everything being relative, advertising is infinitely better now than it was before 1904, when the first club was organized, and, conscious of laxity the leaders go in periodically for resolutions of amendment. I used to think they meant it so, full of enthusiasm during one of the conventions, I actually spent an entire night preparing a radio broadcast, which later told the world that "all advertising people do not approve all advertising", and that if they would only be patient and forgiving, that convention was going to mark a cataclysmic change. That year's set of amendments was the most beautiful thing to see, and to hear them read would just make your heart bleed.

Still thinking they meant it all, I took courage and wrote a letter to about 30 agencies that handled cosmetic advertising (with specific accounts on which it was obvious that I could be useful), telling some special executive that since cosmetic advertising seemed to be suffering from paucity of ideas and malnutrition (stupid and uninformative to the point of being absolutely dumb was what I meant) perhaps they might be glad to confer, and so forth. Well, of the 30, personally directed letters, only four of the recipients had the courtesy even to acknowledge the letter. I continued to moralize about it in articles and talks, but things seemed to become worse, so I resigned my office and membership. Oddly enough, I have done more odd jobs in advertising since then than I did before. I do not know what the moral is, but, all things considered, I repeat that I think your proposed regulations are quite fair enough.

Throughout all my activities in connection with this proposed new legislation, I have consistently maintained that these reforms can never be effected solely through the efforts of those who are "on the outside looking in." In May 1933 when I first offered my services to the Department, thinking that my intimate knowledge of the industry ought to be useful to them, the point I tried to make was that a declaration of ingredients on labels was not the first beginning of a scratch in the control of the cosmetic industry, because it is an ineffective way of getting at the vast "beauty industry" behind it. Many thousands who work in this industry have no thought that this bill will affect them at all, so they are due for a shock.

It is with this group that I have been working during most of the last 10 years. Related as it is to one of the oldest known trades, hairdressing, it presents a united front that is as solidly fortified against outsiders as the rock of Gibraltar. You could never hope to control or effect reforms within such a group without its own consent. And you actually have that, because some of its most influential leaders have been present at all these hearings and filed statements expressing general approval provided that a few suggested alterations were made in the definitions. And now most of these have been made.

The tactics of the militant reformers would accomplish absolutely nothing with a group like this. Fortunately, I have come to know

them rather well. I have been made welcome among them; I can talk to them in their own language; and they know that I am working for their best interests—lately, almost exclusively on improving educational standards and their professional status, too, have had books published; and nearly 200 articles. They have been successful in their way, but they do not figure in the lists of best sellers, nor even in certain "selected bibliographies", probably because they are helpful, rather than destructive.

Through all this period, I have consistently expressed myself as favoring legislation for those in this industry, whether they like it or not, but I have always promised them I would support only the right kind of legislation. Last year, I also promised Senator Copeland that if he would propose some measure that would be more fairly protective and not entirely punitive, I would gladly do what I could to further it. Because I think now that S. 5—insofar as it affects cosmetics, and with at least a few of the amendments that have been suggested in the constructive criticisms of some of these witnesses—will react only to the betterment of the cosmetic and beauty industries, I returned to these hearings so that I could fulfill both my promises in person.

Thank you very much.

Senator CLARK. Dr. Cook?

STATEMENT OF E. FULLERTON COOK, CHAIRMAN OF THE COMMITTEE OF REVISION OF THE UNITED STATES PHARMACOPOEIA

Dr. COOK. Mr. Chairman and members of the Senate committee: My name is E. Fullerton Cook, and notwithstanding recent testimony before this committee I am still chairman of the revision committee of the Pharmacopoeia of the United States.

Mr. Bigelow, a few moments ago, inadvertently, of course, made the statement that Dr. Beal is chairman of the revision committee of the Pharmacopoeia. Dr. Beal is the chairman of the board of trustees of the Pharmacopoeia convention, which is a business organization of the Pharmacopoeia.

I think it would be desirable also for me to make several other corrections which were placed in the record by Mr. Bigelow. He mentioned that Mr. Lynn was president of Eli Lilly & Co., again I think an inadvertent statement, because Mr. Eli Lilly is president of that company.

Mr. Bigelow also made a statement in a general way that all products admitted to the Pharmacopoeia of the United States were simply taken from the creations of drug manufacturers. In the new Pharmacopoeia a number of the most important developers of medical science will be incorporated, and I just mention several of these. He referred to ephedrine. Ephedrine was discovered and placed before the scientific world by a group of medical men in the University of Pekin, taken from a drug known in China for 2,000 years.

Insulin, one of the most important of our modern medicines, was developed by a group of medical or research men headed by Dr. Banton and associates in the University of Toronto.

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Liver extracts were developed by a group of men in the Harvard medical college. Dr. Minnott, who has just been given the Nobel prize, was the discoverer of this product.

Diphtheria antitoxine was discovered by Berry and his associates in Germany. I am simply citing illustrations of the rather loose or inaccurate character of that statement.

I also would like to call attention to the fact that the National Formulary, and I know, or at least I am sure it applies to the Pharmacopoeia, have definitely established the policy that when there were specialties of the trade-marked products on the market, well-known medicines, or perhaps well-known medicines, that neither of these standard compendiums would duplicate exactly the character of these controlled products, believing that to be an unethical and undesirable policy of purposely changing the flavor or the color so that there would not be a simulation or even a substitution of these trade-marks, which accounts for the fact of the Federal inhalants, for instance, of which there are many older if introduced into National Formulary will not be an identical product with any of the others that are trade-marked or controlled products.

I also wish to call attention to the fact in my judgment Miss Edwards, who appeared and objected to the variation clause as proposed by the Food and Drug Act in S. 5, Committee Print No. 3, evidently misunderstood some of the provisions of it, inasmuch as the Department of the Food and Drugs Administration and its attorneys I understand have interpreted the meaning of this clause to maintain the identity of the product, and the variation clause primarily allows a variation in print where that is considered desirable and probably in certain other features when clearly indicated on the label.

I ask for the privilege, however, of saying a few words on this bill for other than the purposes I have named, although it seemed important that they should be referred to.

I desire to present the following statement in the record for the information of the Senate committee in support of the so-called "varying clause" as written in S. 5, Committee Print No. 3, page 14, lines 10, 15, and 18——

Senator CLARK. That may be placed in the record.

Dr. COOK. Starting with the following wording:

No drug shall be deemed to be adulterated under this paragraph.

And so forth.

This clause was objected to by Dr. Fischelis at the first session of this hearing on last Saturday. He was correct in stating that an "official title", that is the name of a medicine as recognized in one of the proposed official compendiums, when carrying no qualification, rightly implies conformity with all official requirements. This proposed legislation demands such compliance, under those circumstances, and that is correct and necessary.

It is my understanding, Mr. Chairman, that Dr. Beal, who has been referred to, and whom I shall refer to in a moment as an authority on this question has given his full approval of this variation clause as worded in S. 5. I understand that he gave that assurance. He did it to me personally in the letter. And as far as I know that is entirely satisfactory to him as a variation clause, and covers the legal points to which I shall refer in a moment.

Senator COPELAND. I wish at your convenience you would look at Dr. Beal's letter, because as I remember it he had an alternative plan. Do you remember about it, that if we did so and so over here [indicating] it was all right, but if we made a change there we would have to make a change in the next page?

Dr. COOK. In discussing this question with him on a number of occasions within the last year I know that he objected to the inclusion in the first part of the paragraph of the words——

Senator COPELAND (interposing). "Identity"?

Dr. COOK. "Definition and description", and you have omitted those.

Senator COPELAND. Yes.

Dr. COOK. So I believe, and in the last week he has written me in his judgment the variation clause as written in this act is a very satisfactory document.

Senator COPELAND. He told me that if we inserted the word "identity" on line 23 of page 12, as Mr. Bigelow suggested, that then we would have to make another change over on the other page, but if that word "identity" were left out on page 12 it would be a very satisfactory arrangement.

Dr. COOK. I could not speak for him in that respect, but I know he has expressed approval of this clause as written now of this variation clause to which I have just referred.

However, in the opinion of many who have studied food and drug legislation, permission to prepare medicines which differ in some particular from the official requirements is believed to be an important provision of such an act. There are at times legitimate needs by physicians in their practice, for strengths other than those established as standard by the Pharmacopœia. For instance, half-strength may at times be indicated for such products as ointment of ammoniated mercury or tincture of iodine and many other illustrations could be cited. But the most important reason for including a clause in this act to permit a variation from the official requirements, in the opinion of the members of the board of trustees of the United States Pharmacopœia and also in the opinion of a number of responsible officials of the American Pharmaceutical Association, is the difference which the clause makes in the legal status of the act with respect to its constitutionality.

When the first Federal Food and Drugs Act was passed in 1906 this question of delegating legislative protest to somebody other than the Congress of the United States or a State legislature, had already been studied and, in fact, certain State acts had, before that time been declared unconstitutional on that ground. Those who assisted in the drafting of the Food and Drug Act of 1906 including Dr. Harvey W. Wiley, Prof. James H. Beal, the present chairman of the United States Pharmacopœia board of trustees and Prof. Joseph P. Remington, at that time the chairman of the United States Pharmacopœia committee of revision, intentionally included a "variation clause", believing that the insertion of this proviso prevented a successful attack upon the act on the point of its constitutionality. While this point is debatable, it was sustained by the opinion of a

prominent attorney, C. Clinton Rhodes, of Philadelphia, who was retained by the United States Pharmacopœia board of trustees, immediately following the passage of the act in 1906, to pass upon the constitutionality question.

Mr. Rhodes' brief on this point fully supported the position of those who drafted the original act and he cited legal justification for it as evidenced by similar important decisions already on record.

Although that was almost 30 years ago Mr. Rhodes only recently, in a personal conversation, stated that he knows of no court decisions since that time which would alter the opinion he expressed on that point in 1906. It must be remembered also that during the 29 years since the act was passed the officials of the Food and Drug Administration have successfully prosecuted under its provisions many hundreds of cases and, so far as I know, the question of unconstitutionality was only raised once and then it was ruled out by the judge as having no justification.

Dr. James H. Beal, the present chairman of the United States Pharmacopœia board of trustees placed a brief on this question in the records of the United States Pharmacopœia board of trustees at the annual meeting of the board held in May of 1934, following the Senate committee hearing on S. 2800, last spring.

The members of the United States Pharmacopœia board unanimously supported Dr. Beal's opinion at that time. They know that Dr. Beal's judgment on this question is supported by legal training and by 40 or more years of intensive study of food and drugs legislation, both State and Federal. They have confidence on his legal opinion on such questions and know that this record for courageously sustaining the rights of the public and of the professions of medicine and pharmacy is widely respected by many who are familiar with the legal side of such matters.

I am taking the liberty of entering into the records of this hearing Dr. Beal's statement to the board of trustees on this point. Dr. Beal wrote as follows:

Our contention has always been that the particular language employed in referring to the Pharmacopœia in the present Food and Drugs Act, coupled with the variation clause, takes it entirely out of the class of cases which have been held to constitute a delegation of legislative authority.

You will recall that under the present Food and Drugs Act if a manufacturer employs an official title, without qualification or explanation, his product must comply with the U. S. P. standards of "strength, quality, or purity." If the preparations do not bear a U. S. P. title, then no such statements need be made. Nowhere in the act is it declared that the Pharmacopœia shall be considered as the standard for drugs and medicines, or that manufacturers shall comply with its requirements.

This wording of the statute was based upon the following theory:

1. That the main object of the law is to prevent misrepresentation and untruthful statements upon the labels of drugs and medicines.

2. That the use of a U. S. P. title without qualification or explanation virtually amounts to a representation that it is a U. S. P. preparation, and that it meets U. S. P. requirements.

3. That if when employing a U. S. P. title the manufacturer departs from U. S. P. requirements, the fact of such departure must appear on the label in order to avoid misrepresentation.

In other words, the present law does not compel the manufacturer to comply with the Pharmacopœia, but only that he shall tell the truth when he departs from it. No matter how frequently the text of the Pharmacopœia is changed, the manufacturer's liability remains unaltered. He is required only to state how his preparation differs from U. S. P. standards if he employs a U. S. P. title. If he employs some other title he may follow any standard he chooses. It is simply the rule of common honesty as applied to Pharmacopœia products.

It is upon this option afforded by the law, either to meet U. S. P. requirements when using a U. S. P. title, or to state the nature of the variation therefrom that we have relied mainly to refute the charge of unconstitutional delegation of legislative authority to the U. S. P. Convention or to its revision committee. If the law only compels the manufacturer to label his product so as to avoid misrepresentation, his substantial rights under the law cannot be affected no matter how frequently the standards of the Pharmacopœia are altered.

You will notice that Dr. Beal there emphasizes the fact that the label should state the difference in which the preparation differs in sense. This is his own brief.

Again, speaking personally, I trust that my position on this question is not misunderstood. I have no sympathy with a provision in this act which would permit deviation from the standards of the U. S. P. on N. F. medicines if that deviation could be used to bring about deception or fraud either to the public or the professions, but I believe that is prevented by the provisions of S. 5 (Committee Print No. 3), since the manufacturer must clearly state upon the label the manner in which the preparation differs in any essential particular from the standards of the official compendiums.

I have confidence in the intelligence and personal integrity of the vast majority of those who will manufacture or dispense these important official medicines, which so largely involve the health of this Nation, and believe that we may count upon this provision in the proposed act, which requires that the exact truth must be stated in unmistakable terms upon the label of the medicine, to prevent fraud or deception.

Thank you very much.

Senator CLARK. The Chair once more requests witnesses who have prepared statements to file them rather than read them. There are still 25 witnesses who have applied to be heard, and the committee is desirous of giving everybody a fair opportunity to be heard, but in view of the fact this subcommittee simply reports the hearings to the full committee, unless witnesses like to hear the sound of their own voice there is no particular purpose to be served in insisting on reading a prepared statement.

Dr. Prescott?

STATEMENT OF DR. SAMUEL C. PRESCOTT, HEAD OF THE DEPARTMENT OF BIOLOGY OF MASSACHUSETTS INSTITUTE OF TECHNOLOGY AND DEAN OF SCIENCE

Dr. PRESCOTT. Chairman Clark and Senator Copeland, my name is Samuel C. Prescott. I am the head of the Department of Biology and Public Health of the Massachusetts Institute of Technology and Dean of Science in that institution.

I have been a bacteriologist for 40 years. I have been president of the Society of the American Bacteriologists. I have also been a member of the Laboratory Section of the Public Health Association for nearly that length of time. In these years I have from time to time carried out bacteriological researches for members of the National Association of Insecticide and Disinfectant Manufacturers

Association, and for the National Committee of Manufacturers of Antiseptics. I am appearing here to present my own views, and also by their request. I would like to say at the outset that so far as my personal feeling is concerned I approve of the intent and purpose of the proposed bill. The criticism which I wish to make today refers only to one particular provision of the bill, and that has to do with the matter of disinfectants and antiseptics.

I am appearing here to urge clarity of statements as to the meaning for the benefit of scientific workers and for those who are concerned with its definitions and application.

I feel that there is perhaps no need of special legislation on this point. For many years the Food and Drug Administration has handled the problems connected with this industry in a highly scientific and satisfactory way I think, and it seems to me there is little, if any, need of further legislation on this point.

Senator COPELAND. Doctor, it is your view that (j) and (k) might be omitted and still the products which are intended to be covered by (j) and (k) would still come under the bill to the extent of giving protection to the consumer?

Dr. PRESCOTT. I feel that, sir; Senator Copeland.

If I may speak now definitely on those paragraphs, in paragraph (j) the four terms, germicide, antiseptic, disinfectant, and bactericide are used synonomously. There may be some difference of opinion on the meaning of "antiseptic", but it seems to me for the purposes of this bill we may take the definition which has been set up by the Food and Drugs Administration, and which is presented in Circular 198 on page 10, which starts with the statement that—

> According to current usage the word "antiseptic" has two meanings; to kill bacteria or to prevent their growth, depending upon the use of the product. Products such as salves, ointments, and dressings that remain in contact with the body for long periods of time, may be designated properly as antiseptics if they inhibit the growth of bacteria. On the other hand, mouth washes, douches, gargles, and preparations of like nature are in contact with the body for but brief periods of time and exert negligible inhibitory action. These may be described properly as antiseptics only if they will destroy bacteria under the conditions of use; that is, in the dilutions recommended and in a period of time comparable to that in which they would have an opportunity to act when used as directed.

In relation to the use on or within the body I would like to point out the importance in this matter of the time factor, during which the substance acts, and to emphasize that in the contact between antiseptic substances and body fluids, or possibly with water extracted from the tissues there may be reaction between these substances so that the antiseptic substance is diminished in strength.

I would further point out that not all antiseptics are used in the same way, and the time factor enters into that as well. It is a matter of common knowledge and experience that if we use, for example, tincture of iodine on the surface of the body, it remains active for a considerable period of time; whereas on the other hand, if we make use of alcohol prepared for this purpose, the effect is immediate but is not lasting. Those two things then differ very much in the matter of application and duration of time.

So in paragraph (j) of section 402 it seems to me that there is a logical objection, looking at this subject from the scientific or academic standpoint, to the use of the terms manner, and duration of application.

As a teacher of bacteriology, and as one who has occasion from time to time to carry out research involving tests of this sort, I would like to emphasize that there is great necessity for exactness of method in the tests which we apply to antiseptics. These test methods which we now have, and which are used by the Food and Drug Administration, have been worked out as the result of much research over long periods of time and careful study. We have found, as all those who have worked on them have found, that the factors of time, temperature, dilution, the type of organism which we use for test, the method of cultivation of that organism and the materials in which we grow the organisms, or carry out our tests are of great importance. These matters have been developed not in any one laboratory, but in many laboratories, hospitals, and medical schools, technical schools, in the Public Health Service, in the Department of Agriculture in one or more laboratories, and in the research laboratories of various manufacturers.

As a result these researches, standard methods, if I may so speak of them, have been evolved. They have received general approval, and they can properly be spoken of as "standard methods." I think that we should continue to expect that those standard methods are to be used for a good while to come. Some of these have been in use for years in the Food and Drugs Administration and have been adopted as official. They are accepted by bacteriologists everywhere. I should like to see one of these methods introduced into this paragraph (j), and for that purpose a modification of the present paragraph (j) has been prepared. This has already been referred to by Dr. Reddish in his comment on this bill. I think the introduction of such a definite method would not interfere with further developments of methods for the testing of antiseptics, and I feel quite certain that as new methods are developed and receive wide-spread approval it will be quite possible for the proper and best methods to be introduced into the law by means of amendment if they should be found to be necessary.

I would like to say a word about the Chestnut decision of 1932. In that decision the word "antiseptic" was defined as something which does not of itself convey the idea of particular strength or degree, or is a word not equivalent in meaning to the word "germicide", and at another place it is mentioned as something which has only a tendency to prevent putrefaction or decay, not to infer any particular potency in connection therewith. The implication which was established in that particular case is that partial restraint of growth constitutes an antiseptic condition, and that a substance which produces such partial action is an effective antiseptic. I can very readily believe that this opinion is not accepted by bacteriologists in general. I can readily believe it may be objectionable to the Food and Drug Administration, and I bring that up here merely as an illustration to make it easier to emphasize the need for definite statements of minimum standards in the law, and to have a more exact formulation of methods of evaluation of disinfectants which bacteriologists everywhere can use when it is necessary to compare these products. By the use of standard methods, which I have al-

ready mentioned, it is possible for bacteriologists in many laboratories to secure what are practically substantially uniform results. I think that manufacturers should know and have a right to know the methods by which their products are to be tested and how they are to be officially examined. And it is certainly very desirable for us who are in the teaching profession to know the methods which are to be used, not only in the Department but also among the manufacturers themselves.

I have already mentioned the difference in individual cases. Individual needs and reactions vary very much. The treatment we will give to a cut or scratch is very different from that which we might apply to a lacerated or dirty wound, or to a very extreme skin irritation. That leads me again to emphasize the desirability of eliminating the terms, manner, and duration of application.

There is a second point in this paragraph (j) which I would like to mention, and that is the indefiniteness of the method of test which is there set forth. As to the method of evaluation the wording here to describe how a test shall be applied brings out the fact that it may be compared to a 1-to-80 phenol solution. Bacteriologists everywhere recognize the effectiveness of a 1-to-80 phenol solution, but I would like to emphasize that we not only would say those products may be compared to a 1-to-80 solution, but that they should be compared always by the same method and technique. It is impossible to get satisfactory results if we set up one method of examination in the standardizing laboratory and then use another method of examination or comparison, for the study of antiseptic effect. When we do not use the same method of comparison the results that we get are not directly comparable. So it seems to me that the wording should be changed here so that if we are going to use this wording at all we should say that the same method should be followed. In order to make that exact we have suggested a wording for paragraph (j) which calls for the test carried out in the following manner——

Senator COPELAND. Excuse me, Doctor. Is this that you are about to read the proposed change that you and Dr. Little apparently agree upon should be the substitute here? Do you agree with Dr. Little in his position on this matter?

Dr. PRESCOTT. I have not had any talk with Dr. Little. I agree with Dr. Reddish.

Senator COPELAND. Yes, sir; I mean Dr. Reddish. And that is what?

Dr. PRESCOTT. That is an in vitro method, a test which we carry out in the laboratory in test tube culture, because I believe that today that is the only exact method of comparison which we have available.

Senator COPELAND. Then as I understand the matter, the substitute for paragraph (j) which you are talking about and that Dr. Reddish spoke about would be satisfactory to you.

Dr. PRESCOTT. Satisfactory to me; yes, sir, personally.

Senator COPELAND. But beyond that your preference would be to omit the entire thing; is that right?

Dr. PRESCOTT. I think the Department can administer its affairs perfectly well if (j) and (k) are completely omitted from this bill.

Senator COPELAND. But you are going to offer for the record a substitute?

Dr. PRESCOTT. A substitute in case it is felt necessary by your committee to have some reference to this matter in this bill.

Senator COPELAND. All right.

Dr. PRESCOTT. And I shall offer also a substitute for section (k) in the same way.

Senator COPELAND. All right.

Dr. PRESCOTT. Then we believe there should be a uniformity of method in testing. We believe also that there are certain portions of this bill with reference to how new methods may be set up which should be modified. Those refer to section 703, paragraph (d), where it is stated that these methods may be set up without notice or hearing. It is almost impossible in a business like the preparation of antiseptics and disinfectants for the manufacturer to meet the requirements of a law when he does not know in advance what those requirements are going to be. I think there should be no change without preliminary notice or hearing.

There are certain points in regard to section (k) which I should like to mention also, and specially to object to the terms, the manner, and duration of application in that case.

If I may, in order to save the time of your committee, I will present this statement which is somewhat more complete than I have given it here.

Senator CLARK. It may be received and filed.

Dr. PRESCOTT. I thank you for giving me this opportunity to speak.

(The statement referred to is as follows:)

A STATEMENT BY DR. SAMUEL C. PRESCOTT, DEAN OF SCIENCE, HEAD OF THE DEPARTMENT OF BIOLOGY AND PUBLIC HEALTH OF THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY, AND PAST PRESIDENT OF THE SOCIETY OF AMERICAN BACTERIOLOGISTS, MADE BEFORE THE COMMITTEE ON COMMERCE OF THE UNITED STATES SENATE IN REFERENCE TO PARAGRAPHS (j) AND (k) OF SECTION 402 OF S. 5 (COMMITTEE PRINT NO. 3) ON BEHALF OF THE NATIONAL ASSOCIATION OF INSECTICIDE AND DISINFECTANT MANUFACTURERS, INC., AND THE NATIONAL COMMITTEE OF MANUFACTURERS OF ANTISEPTICS

At the outset I wish to express hearty approval of the general purpose of the proposed bill, S. 5, and of its intent to protect the public against fraud, deception, or misrepresentation, and to prevent the merchandising and advertising of products deleterious to health or inimical to public welfare.

However, with reference to one particular division of the bill, viz. that pertaining to germicides, disinfectants, and antiseptics, I wish to present certain objections, and to urge that these provisions of the bill be modified in such a way as to give a clear statement of their meaning, and to meet the approval of bacteriologists, and other scientific workers who are concerned with their definitions and applications. Incidentally, I feel strongly that there is no need for a special reference to this matter in the bill under consideration because of the general provisions applying to adulteration or false advertising. But if it is necessary to make such special provisions, a modification of the respective paragraphs of the proposed bill should be made.

In paragraph (j) of section 402 of the proposed bill (S. 5), the four terms, "disinfectant, germicide, bactericide, and antiseptic", are used synonymously. While there may be some disagreement among scientists as to the exact meaning of the first three of these terms, they may be regarded as referring to products or effects having to do with destruction of bacteria. There exists, however, definite difference of opinion as to the definition of the term "antiseptic." For the purposes of this bill we may accept the description given on page 10 in circular 198 of the Department of Agriculture, which states:

"According to current usage the word 'antiseptic' has two meanings, to kill bacteria or to prevent their growth, depending upon the use of the product. Products such as salves, ointments, and dressings that remain in contact with

the body for long periods of time, may be designated properly as antiseptics if they inhibit the growth of bacteria. On the other hand, mouth washes, douches, gargles, and preparations of like nature are in contact with the body for but brief periods of time and exert negligible inhibitory action. These may be described properly an antiseptics only if they will destroy bacteria under the conditions of use; that is, in the dilutions recommended and in a period of time comparable to that in which they would have an opportunity to act when used as directed."

In regard to disinfectants or antiseptics for use "on or within the body", there is another aspect which should be made clear, viz, that of the time factor. A reaction between the antiseptic substance and the body fluids or tissues may take place, or its effective strength may be weakened after a fairly short or prolonged contact. In either case it is a matter of common knowledge and experience that in some cases new applications of the germicide or antiseptic may be necessary if it is desired to continue the destructive or inhibitory action. It is therefore clear that no fixed statements as to the manner of application, or the duration or frequency of application can be made which will be useful or satisfactory under all circumstances. The following familiar examples of the varied use of such products will illustrate this contention. Tincture of iodine, for example, as used on abrasions and other skin injuries gives practically continuous or prolonged germicidal or antiseptic action following a single application whereas in the case of alcohol the germicidal action may be regarded as immediate but not lasting.

Another objection to the present wording of paragraph (j) and (k) of section 402, has to do with the testing of germicides and antiseptics. It is clear that the testing of the efficiency of any product should be done by exact and careful procedures in order to gain positive and definite knowledge of the really effective strength of the product under examination. The testing of disinfectants and antiseptics has been given very careful study in the past and recognized methods have been developed over a long period of years of research, setting up the exact conditions of time, temperature, and dilution, and specifying representative test organisms, and their method of cultivation, for the purpose of evaluation of the products of this class.

These investigations have been conducted by many bacteriologists in hospitals, medical and technical schools and colleges, and the results have been considered by committees of such professional societies as the American Public Health Association and the Society of American Bacteriologists. Much work has also been done in manufacturers' research laboratories as well as in certain divisions of the Federl service such as the hygienic laboratory of the Public Health Service and in the laboratories of the Department of Agriculture. As a result of this work certain testing methods have been evolved, some of which have received general approval, and these recognized methods can properly be spoken of as "standard" methods.

Some of these approved methods have been in use for years in the laboratories of the Food and Drug Administration and have been adopted as official methods of test by the Department of Agriculture. They have stood the test of time and are generally accepted by bacteriologists throughout the country.

In an imporant decision rendered by Judge Chestnut of the District Court of Maryland on January 5, 1932, the opinion was expressed that "the word 'antiseptic' does not of itself convey the idea of any particular strength or degree" * * * and "that the word is not equivalent in meaning to the word 'germicide'" * * * and further that "to say that a substance is antiseptic is merely to affirm that it has a tendency to prevent putrefaction, decay, or the development or increase of bacteria; and not to affirm any partilular potency in connection therewith."

By this decision the implication is established that even partial restraint of growth of bacteria constitutes antiseptic action, and that a substance which produces such an effect is therefore an antiseptic. Obviously, this opinion is at variance with that generally accepted by many bacteriologists and other scientific workers. No doubt, it has been objectionable to the regulatory office of the Food and Drug Administration, and properly so, because it has weakened the power of the Administration to enforce the law and to protect the public from fraud and deception. This fact emphasizes the need for a statement of the definition of terms and of setting up minimum standards in the law, and also of an exact formulation of the methods by which the evaluation of the antiseptic substances shall be carried out. This is necessary not only for the information of the bacteriologists in professional or teaching laboratories but of those concerned with the manufacture and production control of this class of products. Certainly the manufacturers are deeply interested in these procedures; they may assume it to be their right to know in what manner their products are to be officially examined.

It is obvious that there are numerous ways in which a disinfectant or antiseptic may be used and that these may vary greatly in the manner and duration of application. Moreover, the individual need of and the individual reaction to the active agents of this character may also vary greatly. It is obvious that the external application of an antiseptic to a fresh superficial cut or scratch may be intended only for a practically momentary action while for a wound of more serious character, a longer and more continuous treatment may be necessary. It is, therefore, manifestly impossible for the label to bear a description of each and every manner and duration of use which may be made of a product of this character. What the user desires to know is that the product has actual germicidal or antiseptic value when a specified dilution of it is used. It therefore seems to be not only necessary but often misleading to attempt to specify the exact manner and duration of application since it might happen that the exact method specified could not be complied with at the moment or under the conditions when most needed. Clearly the terms "manner and duration" cannot have any exact or scientific significance or interpretation. These terms are indefinite and open to misconstruction and, in my opinion, have no place in a law of this nature.

An objectionable feature is noted also in the wording of the paragraph with reference to the standardization or evaluation of the germicidal power of antiseptics. It seems to be entirely proper that a direct comparison should be made with a 1–80 dilution of phenol. This definite chemical substance is universally recognized as being positive in its action on the class of microorganisms which one ordinarily desires to combat with the aid of antiseptics. Since Staphylococcus aureus is the most common cause of infection, and in general the most resistant to germicides, it has been generally accepted in America as the best organism to employ in quantitative tests. Years of experiment and research have established methods by which it can be used in laboratory procedures in vitro (that is, in culture tests made in the usual laboratory apparatus, test-tubes, flasks, etc.) with high precision, providing that the temperature, the quantity and age of the culture, and the time of contact between culture and antiseptic and character of the culture medium are all accurately controlled. Using such exact standard procedures, bacteriologists in various laboratories can obtain results in substantial agreement. It would therefore seem not only wise but essential that the method of measurement of germicidal value (p. 18, line 25, and p. 19, lines 1–4) should be explicitly stated, and that in all instances of direct comparison the same method should be used. That is to say, if it is required to test the germicidal strength of a preparation by comparison with a 1–80 phenol solution, any such tests should be carried out by the same method, as employed in the case of phenol. The inexactness of the words "a standard method" in the two places in the text of paragraph (j) where these words occur leaves an opportunity for ambiguity, and for the possibility of introducing a second method which in fact is not comparable with the method involving the use of the 1–80 solution of phenol referred to above. Because of this looseness of expression, whether by intent or by accident of phrasing, the statement is objectionable.

It would be unscientific and unfair to demand one standard of the manufacturer and to permit another to be used by the regulatory agencies of the Government. The careful, reputable and law-abiding manufacturer who seeks fully to conform to regulatory requirements is at least entitled to the knowledge which would enable him to test his product by the same standard imposed on him by the law.

A further objection to paragraph (j) is found in the statement that "all standard methods for the purposes of this paragraph shall be prescribed by regulations as provided by sections 701 and 703." Special reference is made here to that portion which involves paragraph (d) of section 703 wherein temporary regulatory procedures may be promulgated without notice or hearing, to remain in effect for a period of 180 days. It would seem reasonable to exclude all references to paragraphs (j) and (k) from the provisions of this section, in view of the fact that without notice or hearing manufacturers would not be able to meet such requirements because of lack of information, and bacteriologists and other scientific workers whose constant attention must

be given to the testing and composition of products, would not be in a position to make the necessary adjustments of formulæ and to apply the new methods of test that might be set up. The business of preparation of disinfectants and antiseptics is unique in this respect, viz., that every batch or lot must be subjected to tests of antibacterial quality; lack of definite knowledge of new requirements might easily result in ruin because of seizures, fines or suits, when as a matter of fact there might be the fullest intent on the part of the manufacturers to meet all legal obligations and standards.

Attention should also be directed to the fact that in several States legislation bearing on the testing and control of disinfectants and antiseptics is already being formulated. Since in many, if not in all, cases this legislation will probably follow closely in form that of the Federal law it is especially desirable that the utmost clearness and definiteness of expression, and the exact statement of test methods to be enforced should be written into the legislation to be passed by the Congress. It would be unfortunate and anarchistic to have laws in the several States similar in form but widely different in their interpretation and enforcement.

Therefore, I offer for your consideration the following modified form of paragraph (j) of section 402, in which a specific standard method of testing is incorporated, but which differs but slightly in its wording in other respects, and which I believe, would fully meet the meaning and intent of the printed wording in the proposed bill.

"SEC. 402. A drug shall be deemed to be misbranded—

"(j) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for use on or within the body, except as provided in (k) of this section, and its labeling fails to bear a plain and conspicuous statement of such use, including the strength or dilution, and if 5 cc of the dilution specified is not capable of killing in vitro within 5 minutes at 37° centigrade not more than 0.5 cc of a 24-hour broth culture of staphylococcus aureus of such resistance that not more than 0.5 cc of this culture when tested in vitro at 37° centigrade is killed by 5 cc of a 1–80 aqueous dilution of phenol, in 10 minutes but not in 5 minutes: *Provided*, that no drug shall be deemed to be misbranded under this paragraph by reason of any advertised use or by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical professions, or appears only in scientific publications of these professions.

This wording, I believe, provides the legalization of the present procedure which is used by the Department and which its representative has verbally stated in consultation on this subject to be its sole and special desire, aim, and intent in carrying out future work.

In reference to the above-proposed wording, I wish to add the following remarks:

It is recognized that there are organisms other than staphylococci or streptococci which may be found in or associated with suppurative processes. It is conceivable that some of these organisms might not be destroyed by certain germicides having the strength indicated in the suggested draft of paragraph (j). But it should be emphasized that these bacteria are not of general significance and that, as a rule, their power to produce injury or infection is very low. Only in very rare cases would they not be destroyed by germicides of the strength indicated in the above-mentioned paragraph. Since we recognize that the object of this bill is to give a broad general protection to the public, I believe that this objective is amply reached by the proposed wording of paragraph (j).

While therefore protesting against the wording of the present bill, may I offer the constructive suggestion above, with the hope that it may meet every situation and receive general approval?

The wording of paragraph (k) of the same section may be objected to for somewhat similar reasons. Here again the use of the terms "manner and duration of application" appears to be improper for the same reasons as specified for paragraph (j) viz. because it is impossible to give exactly the manner or to state accurately the time of duration of application; this must perforce vary with the sensitiveness of the individual to the product, the part of the body treated, the reaction with body fluids and the temperature and other conditions.

What seems to me of importance in regard to paragraph (k) is the certainty that the antiseptic in the strength and dilution recommended, when tested by a standard in vitro method, should have the power to restrain bacterial action by preventing the reproduction of bacteria.

In keeping with this idea I offer also a slightly modified revision of paragraph (k):

SEC. 402. A drug shall be deemed to be misbranded—(k) if it purports to be or is represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body, and its labeling fails to bear a plain and conspicuous statement of such use, including strength or dilution, and when tested by a standard agar-plate method for determining inhibitory effect it fails, in the strength or dilution prescribed, to prevent the growth of a culture of staphylococcus aureus of the resistance specified in (j) of this section: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of any advertised use or by reason of failure of its labeling to bear a statement of any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical professions, or appears only in scientific publications of these professions.

Senator CLARK. Mr. Peterson?

STATEMENT OF H. C. PETERSON, SECRETARY AND MANAGER OF THE NATIONAL ASSOCIATION OF RETAIL GROCERS, CHICAGO, ILL.

Mr. PETERSON. Mr. Chairman and members of the committee, my name is H. C. Peterson, secretary and manager of the National Association of Retail Grocers, Chicago, Ill.

I desire on behalf of our 40,000 members, with 80,000 others for whom we have proxies, in looking as to their legislative interests to endorse fully the bill under consideration here with the amendments proposed by Charles Wesley Dunn, and I would like also permission to file a brief.

Senator CLARK. That may be filed.

Senator COPELAND. We are much obliged to you for your brief and to-the-point statement, and particularly for your endorsement of the bill.

Mr. PETERSON. Thanks very much for this opportunity to come here.

Senator CLARK. Mr. Snyder?

STATEMENT OF J. P. SNYDER, CHIEF CHEMIST OF THE NORWICH PHARMACAL CO.

Mr. SNYDER. Mr. Chairman and members of the committee, my name is J. P. Snyder, and I am chief chemist of the Norwich Pharmacal Co. I just want to take up about 1 minute of your time and talk to the provision on page 16, no. 2, in which it states it is misbranding in case it is fabricated from two or more ingredients. The name of each active ingredient is not stated. We have heard considerable testimony today as to objections to the committee on the matter of taking out the names and quantity in proportions, and I wish to take the stand that I approve entirely of taking these quantitative formula out for this reason: There are on the market today many, perhaps of considerable value to a number of people—in fact, they are manufactured under royalty, and there are a great deal of restrictions in the contracts drawn between these companies, and if we were required to state the quantitative formula on those

labels, then those formulas become simply the property of anyone who wants to pirate the preparation, and for this reason I wish to particularly request that if it is necessary to make any statement regarding the ingredients that it be limited to simply naming the ingredients, and not specifying the quantitative formula; otherwise, I believe it will simply result in these formulas being pirated more than they are at the present time.

I would like to leave that thought with you.

Senator CLARK. Mr. Godfrey.

STATEMENT OF ROBERT D. GODFREY, COUNSEL FOR THE INSTITUTE OF MEDICINE MANUFACTURERS, AND REPRESENTING STRONG, COBB & CO., INC.

Mr. GODFREY. Mr. Chairman and gentlemen of the committee, my name is Robert D. Godfrey. I am an attorney from Cleveland, Ohio, representing the Institute of Medicine Manufacturers, some members of the proprietary association, and the Strong, Cobb & Co., Inc., private formula manufacturers for over 100 years.

Senator COPELAND. Mr. Godfrey, pardon me for speaking of it, but we have so many witnesses.

Mr. GODFREY. Yes, sir.

Senator COPELAND. I notice you have a prepared statement.

Mr. GODFREY. I have not a prepared statement.

Senator COPELAND. Pardon me. Go ahead.

Mr. GODFREY. We are not opposed to a reasonable regulation of these industries in favor of the consuming public, but we are opposed to an unreasonable regulation of the industries in an unjust manner.

We favor the present and existing law, and the more I hear about the proposed bill before us and the more I study it the more I am convinced that the existing law was exceedingly well prepared.

Senator COPELAND. You do not want any new law?

Mr. GODFREY. Yes, sir; we are in favor of any additions that may be necessary to the existing law, but not on the basis of a total destruction of the existing law, and the certainty produced by the court decisions that have been made under it. Whatever value it has, and I think it has great value, should be allowed to remain and appropriate amendments be made instead of the complete repeal of it, as the present bill sets out to do.

The Copeland bill (S. 5) is substantially the same as the original Tugwell bill (S. 1944) and the Copeland bill (S. 2800) in principle and in theory and in the matter of the detail with which it intends to regulate these industries. The new bill differs from the old only in slight rearrangement and slight amendment.

Senator COPELAND. It has a different number?

Mr. GODFREY. Yes; but, generally speaking it is practically the same bill.

Senator CLARK. Mr. Godfrey, may I interrupt you just a moment? There has been very much hope that we would be able to conclude these hearings today.

Mr. GODFREY. Yes.

Senator CLARK. It is apparent from the number of witnesses remaining it will not be possible to do it, and at the conclusion of this

witnesses' testimony the committee will take a recess until 9:30 tomorrow morning, and the Chair desires to announce at this time that no witnesses who have not applied prior to today's hearing will be placed on the list. As a matter of fact, we had more customers this morning than we had at the conclusion of the hearing the other day.

Mr. GODFREY. As I say, this is practically the same bill, and it leaves very broad and extensive powers in the Secretary of Agriculture to regulate in great detail and to prohibit the sale of numerous valuable consumer products. In my opinion this is a very dangerous bill and should be definitely and is definitely opposed. I do not believe that the amendment to this bill would render a satisfactory bill, fair to the industry and fair to the consumer. Amendments have been attempted for a period of a year and a half, and are still being attempted, so numerous, so voluminous, and so varied in character that I am convinced this bill is beyond amendment in making a satisfactory law.

Briefly speaking, our objections to this bill are, first, that its prohibitive acts are too broadly defined, too vaguely stated, too inaccurately stated, too indefinite, too uncertain to be a penal, criminal statute, which it is.

I also object to the transferring and creating of dictatorial powers in a bureau. We object to the transfer of legislative powers by regulation to the Department of Agriculture with such extensive powers as are created by this act. We object to the transfer of control from the courts to the bureau.

We object to the extreme and unreasonable enforcement powers set up in this act by seizures, both by legal action and without legal action, without notice to the parties concerned, without hearing on technical violations, where the question of imminent danger to public health is in no sense concerned whatsoever, and where such drastic action is wholly unnecessary and ruinous to valuable established businesses.

We are opposed to the transfer of the regulation of this huge amount of advertising from the Federal Trade Commission to the Department of Agriculture for the reason in my opinion the Federal Trade Commission is much better equipped to handle these large and complicated questions.

I will not go into the various phases of the act, the various provisions, as I at first intended, because they have been so completely covered and analyzed by numerous witnesses. Their broad powers, vague definitions, their erroneous definitions, their uncertain definitions in a penal statute, the violation of all of which sends a man to jail, this I am opposed to.

Senator COPELAND. That is, you are against this bill from start to finish?

Mr. GODFREY. Yes.

Senator COPELAND. That is a positive statement.

Mr. GODFREY. In addition to that I have to say this: The method of regulating the food, drug, and cosmetic industries, not only as provided in the existing law but also as proposed in all of the new bills to revise the Federal Food and Drug Act, are not properly devised so as to effectively and practically accomplish the purposes

for which they are intended, without excessive, unnecessary friction, disturbance, and vexatious interference with the industries involved. One of the chief reasons for the failure of this legislation is that they are primarily penal in their nature; that is, they attempt to enforce the compliance with the act upon the industries by criminal prosecutions and seizure of merchandise without notice or hearing upon the merits, both of which procedures are extraordinary, harsh, and unnecessary.

The proper enforcement of a food, drug, and cosmetic law should not be accomplished primarily by sending men to jail for minor and technical violations nor by the sudden and unexpected interference, harrassment, and prostration of extensive business, through this extraordinary remedy of multiple seizures before a hearing has been had. A wise law surely should not resort to such a ruthless method of regulation. In place of such a law a more civilized law should be enacted, which deals intelligently and practically with the industries, not as a band of criminals and bandits, but as the owners and operators of established essential industries in which a reasonable and sensible regulation is desired in the interest of the consuming public.

Senator COPELAND. I want to interrupt you a moment. Do you mean to say that we are dealing with the industry as if they were bandits, robbers, and murderers? I think that is about what you have said?

Mr. GODFREY. Yes; in some instances.

Senator COPELAND. You do not believe we should protect the consumers?

Mr. GODFREY. Yes; I do; but I think it can be done in a more practical and better way.

Senator COPELAND. Your statement is that this bill is discriminatory and harmful to these industries affected?

Mr. GODFREY. Because of the huge list of prohibitions which are criminal offenses.

Senator COPELAND. We were told only a day or two ago the consumer has not been getting any consideration, that this bill is wholly in the interest of these industries affected. Do you agree with that?

Mr. GODFREY. No.

Senator COPELAND. You take a different position?

Mr. GODFREY. I am on the other side of that question, decidedly.

Senator COPELAND. You are a good witness for us.

Mr. GODFREY. Very well; I thank you.

Criminal prosecutions and seizures, as conducted under the present law and as provided for in the Copeland bill, do not give satisfactory protection to the public and, furthermore, prevent an enlightened understanding between the Government and the industries and prevent cooperative compliance with the regulation. Under these laws a conscientious manufacturer or dealer in most cases cannot tell in advance whether he is violating the law until after he has acted by manufacturing and shipping the merchandise in interstate commerce and a prosecution has been instituted and tried. This is archaic and should be abolished by enactment of a new law, providing for a new, different, and sensible method of securing compliance with fair and reasonable regulations in advance of any violation and prosecution.

Criminal prosecutions are generally instituted long after the commodities have reached the consuming public. It is a crude and ineffectual way of advising a manufacturer or dealer of noncompliance with the law. In criminal cases no opinions are rendered and therefore they do not serve as precedents to be used as guides to subsequent manufacturers or dealers.

Seizures of alleged misbranded, and adulterated merchandise are an ineffective means of keeping such merchandise from the consuming public. Although multiple seizures are resorted to only a very small quantity of the alleged merchandise can be kept out of the market by this method. The seizures are made by the Government primarily for the purpose of giving notice to the offender and, secondarily, to cause the offender sufficient trouble in order to force the product off the market. As a general rule the action for libel for condemnation results in a default judgment for the Government because the manufacturer or dealer finds the defense too cumbersome and expensive to be worth while, even though there is a meritorious defense. As a result, the Department of the Government in charge of enforcement and the manufacturers deal at arms' length with each other and only frequently sit down at the same table to frankly discuss the situation. As a result, the Department often uses the threat of seizures and criminal prosecutions as a means of harassing and intimidating manufactures to do the arbitrary bidding of the Department and to changes in the products and changes in labels without inquiry, judicial or otherwise as to the validity of the Department's demands. Such procedure produces a condition of constant warfare between the Department and the manufacturers, rather than a peaceable and sensible meeting to work out a satisfactory solution.

If the Copeland bill becomes a law there will be a tremendous enlargement of the scope of regulation and the powers of the Secretary of Agriculture over these industries, as well as all advertising relating thereto. This will result in a great increase in the number of unavoidable violations, due partly to the extension of the laws and partly to the necessity of interpretation of the new, general, vague, uncertain and indefinite language employed in the new bill. The Food and Drug Administration, the United States courts and the industries will be flooded with new criminal actions and seizures for confiscation, causing a situation similar to the chaotic condition produced by attempting to enforce the prohibition amendment.

An entirely new and different method of procedure in my opinion should be adopted. The industries would be only too glad to cooperate with the Government in an equitable regulation of these trades if they were assured that they would receive a fair hearing and interpretation of the law and that vexatious and unjustifiable prosecutions would not be imposed upon them.

Senator COPELAND. Do you have any doubt about that?

Mr. GODFREY. I have no doubt about that. I have practiced in this industry 20 years, and I feel certain about that. I have failed to come across a case where in my opinion they were not very willing to cooperate.

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Senator COPELAND. No; I meant do you have any doubt your brief would receive any attention and respectful consideration?

Mr. GODFREY. I am presenting what I think on the subject, not with any feeling of animosity, but merely the culmination of my examination of this law, and a study of it over a period of years. We have had this bill for a period of a year and a half.

If confidence could be established between the Government and the industries, practically all of the difficulties in the enforcement of the law that exists at present would be corrected satisfactorily to both sides. The constant threat of seizure and criminal prosecutions without notice in technical, doubtful, and border-line cases, where the industries have acted in all good faith, have produced a situation where the industries have not been free or even given the opportunity to fully cooperate by conference and negotiations with the Government to satisfy their claims. This has prevented an intelligent and businesslike administration of the law. And if the Copeland bill becomes law I can see nothing but strife and grief ahead.

A separate commission, independent of the Department of Agriculture, and similar to the Federal Trade Commission, should be provided for the administration of a new Federal food, drug, and cosmetic law.

Senator COPELAND. Would you prefer to have the Federal Trade Commission take it over?

Mr. GODFREY. No; I think it should be a new commission.

Senator COPELAND. They should have a new commission?

Mr. GODFREY. With a procedure very similar to the procedure in the Federal Trade Commission, because they are able by negotiations and have in the past by methods of calling the parties in informally, and by agreement, conference, and stipulation settle most of the cases without any sort of prosecution being necessary whatsoever, and I maintain in this instance such a situation could be created with procedure of that kind set up.

Senator COPELAND. I find the attitude of the American people is that they are in opposition to new commissions, and think we have too many now.

Mr. GODFREY. I am not here to discuss the attitude of the American people in general. I am willing to discuss any questions as to this bill, and that is the question I am going into now.

Senator COPELAND. Frankness compels me to say I do not think you are representing the American people in the objections you have made. However, that is only my opinion, and you have another one.

Mr. GODFREY. There is a difference of opinion, as there is a difference of medical opinion on these questions.

The members of this commission should consist of men of knowledge and judgment of the industries involved and understanding of their problems, as well as an appropriate interest in the consuming public. The procedure for the administration of the law should be similar to the procedure under the Federal Trade Commission Act. Regulation of the industries by the commission should be accomplished chiefly by private conference and negotiations between the industries and the commission without threats of any kind and for the purpose of securing an efficient, practical, and fair regulation of the industries.

The new Federal food, drug, and cosmetic law should not be a penal or criminal law primarily, by which results are obtained by threats of criminal violations or multiple seizures in order to coerce manufacturers and dealers to follow the arbitrary dictates imposed by the administation. Such harsh remedies as these should be utilized only as a last resort, after all other peaceable means have been exhausted. The problems of adulteration, misbranding, and false advertising are so complicated, technical, and far-reaching in their scope, that they should be worked out after thorough investigation and hearing on the same basis as the question of unfair competition and unfair trade practices among the industries are worked out by the Federal Trade Commission, without criminal prosecutions or extraordinary remedies.

Senator COPELAND. Will you let me interrupt you there?

Mr. GODFREY. Yes.

Senator COPELAND. I have hardly done a thing for nearly 2 years except to have daily conference just like you are talking about.

Mr. GODFREY. Yes, sir; I am aware af that.

Senator COPELAND. I have reached certain conclusions that are entirely different from yours.

Mr. GODFREY. Yes.

Senator COPELAND. Then how could you ever get 2 men, or 3, or 5, to ever agree?

Mr. GODFREY. This is my opinion. I thought it might be well to put it in the record. It may be a little different from any opinion expressed here. It may have some value and it may not. The mere fact we differ does not necessarily decide which one of us is right and which one of us is wrong.

Senator COPELAND. I was only giving you the benefit of a rather prolonged experience in this particular thing.

Mr. GODFREY. Yes.

Senator COPELAND. I have listened, I think, with some degree of patience every day and almost every hour 2 years ago, since last June——

Mr. GODFREY (interposing). I appreciate that; I think you deserve great credit.

Senator COPELAND. And out of that and with the counsel of experts we have presented a foundation for a bill. You see, it is somewhat discouraging to us to have you come and say this is bad from the first page to the last one.

Mr. GODFREY. Maybe so.

Senator COPELAND. And therefore you are not surprised, I suppose, if I comment.

Mr. GODFREY. I expected you possibly would take this position on this question, but I feel very sincerely about it, that if the procedure were changed it would be much better. This not only is a criminal statute as it is here written, but it means there will be a great enlargement which is going to multiply the number of criminal offenses, and the only practical way of securing enforcement here is to use a strong, big stick of criminal prosecutions and seizures immediately without notice. We all know that many of these products do not have to be seized; they are not that dangerous to public health, but under this law they have to be seized.

Senator COPELAND. You have never had any experience in administering a food and drug law, have you?

Mr. GODFREY. I have had experience from the other side.

Senator COPELAND. That is exactly what you have had, experience from the other side.

Mr. GODFREY. Yes.

Senator COPELAND. I have had experience for years in the administration of a food and drug law.

Mr. GODFREY. Yes.

Senator COPELAND. And it is my experience you do need to have a club, not to protect honest men like you, but men who are seeking to evade the obligations that they owe to society. If all the men were honest, as you are, there would be no occasion for any law. That is the reason we have to have laws.

You just put yourself for a moment in the place of the Food and Drug Administration. They are public servants. They are seeking to protect the public. Now, in order to protect the public they have to deal with many unscrupulous persons. You must bear in mind it is the unscrupulous, hole-in-the-wall, manufacturer who has to be reached. It is not the man who goes along with a sense of consciousness he is doing right, but you have got to bear in mind that there are thousands of individuals, not of concerns, but of individuals in America who are seeking all of the time to exploit the public, and to make money out of the disabilities of people, or the belief that they have disabilities. Now, bear that in mind in your discussion. Do not think about these honest concerns you are representing, but you think about the other unscrupulous ones who need to have such supervision as this law proposes.

Mr. GODFREY. I have greater confidence in humanity than you have, and I do not find the people in this industry so that the unscrupulous members are in any such great number as you do. And I do not feel——

Senator COPELAND (interposing). You must be living in a heaven of your own, and I congratulate you. I do not see your wings sprouting, but they will be very shortly.

Mr. GODFREY. Very well. I think there is plenty of opportunity after a conference has been had with a scrupulous or unscrupulous party in the industry, and if he does not comply with proper suggestions under friendly negotiation, then it is time enough to use harsh remedies. But these criminal prosecutions are instituted without notice and these seizures are made without notice, and they are made not only upon the unscrupulous, but they fall very heavily upon the scrupulous as well as upon the unscrupulous, and the schupulous, in my estimation, far, far, outnumber the unscrupulous.

Senator COPELAND. I think that is true. I would not enter into this discussion if the members of the committee who have been eager to go home were here, and the other witnesses have been notified they can come tomorrow.

Mr. GODFREY. Yes.

Senator COPELAND. But as a matter of fact, there is not a thing in this law, and I think I know as much about it as anybody except the real experts, that affects the honest manufacturer, or distributor, or advertiser. It is not right to write into the law provisions that might impose unnecessary hardships upon those who are engaged in honest business. But on the other hand it is necessary that the American people should be protected against the unscrupulous operators, and the purpose of this bill is to deal with the unscrupulous, not with the honest men.

You and your client, I assume, are attempting to do an honest business, and because of that fact you are shocked to think that we even think about the necessity of control, but, my dear sir, those of us who have been in a position to know, realize it is necessary to have a club. It is necessary to have the power, even though that power is not exercised, but the power must be there, or else the protection cannot be given the people.

You have a police force in the city to maintain traffic and also to prevent crime. You have got a police force here in Washington. In connection with this particular problem, in order that those who would seek to do harm to the consumer shall be dealt with in the most vigorous manner it is necessary to have that in order to protect society. I do not think you graps at all, if I may say it, the philosophy of the bill, or the intent of its framers, or the spirit of those who favor the bill.

We have looked with the greatest of patience to those who have sought constructively to change the bill, to point out to us its defects, to suggest new language, but you, if I may say it, are coming to us to tell us it is all wrong, and it is fundamentally defective, and the implication is there must be something wrong with us that we would even think of such things.

Mr. GODFREY. There is no such implication.

Senator COPELAND. All right, go ahead.

Mr. GODFREY. I know you men have gone into this with the utmost good faith and with the finest attitude in the world, but still I do not agree with the results you have produced in this bill, for the reasons I have stated, and I can see no reason for repeating them further at this late hour.

Senator COPELAND. You can go ahead. I will stay as long as you will.

Mr. GODFREY. Instead of criminal prosecution and seizures of merchandise for adulteration, misbranding, and false advertising, the offenders should be cited to appear before the Commission to show cause why they should not cease and desist such practice. The parties cited should be given an opportunity to file an answer and to have a full hearing with the opportunity to present any evidence in justification of their actions. After all of the evidence has been submitted, arguments presented, and conference had with regard to a solution of the controversy, an order or stipulation should be entered by the Commission, either justifying the practice or pointing out an appropriate way of complying with the law. In the event a method of compliance with the law has not been reached by the parties then an order should be made by the Commission to cease and desist at a certain specified time. A review of the findings of the Commission by appeal to the United States Circuit Court of Appeals should be provided similar to that provided by the Federal Trade Commission Act.

The new law should provide a method for submitting labels, and advertising copy to the Commission for approval or rejection before

the same have been used by a manufacturer or dealer, which would eliminate the hazard of inadvertent violation by parties acting in good faith and for the purpose of knowing in advance whether their labeling or advertising was in violation of the law.

No criminal prosecutions nor seizures for confiscation should be made until after hearing has been had before the Commission and a cease and desist order violated. However, upon a showing satisfactory to the court that imminent danger to public health will otherwise result, the United States courts should have jurisdiction to restrain by temporary or permanent injunction the shipment of such article in interstate commerce, and also to order the seizure or impounding of such articles. Seizure and injunction should be allowed only upon such a showing that an emergency existed and that immediate drastic action in the interest of public health were necessary.

Such a procedure and method of administering the Federal food, drug, and cosmetic law would provide a media between the Government and the industries by which they could cooperate in a business-like way to prevent adulteration, misbranding, and false advertising injurious to the public health without unnecessary interference with legitimate business and without prosecuting honest business men as if they were criminals.

Senator COPELAND. The committee will adjourn until 9:30 tomorrow morning in this room. You may file any other material you have.

I wish to submit a statement filed by Dr. Samuel L. Hilton.

STATEMENT BY DR. SAMUEL L. HILTON, CHAIRMAN LEGISLATIVE COMMITTEE, DISTRICT OF COLUMBIA PHARMACEUTICAL ASSOCIATION

It is not my purpose nor the purpose of the members of our organization to comment on many portions of S. 5, committee print no. 3.

Page 2, line 5, (b) the term "drug" for the purpose of this act and not for the regulation of the legalized practice of the healing art, includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances, preparations, and devices, other than food, intended to affect the structure or any function of the body. We submit that nothing in this section refers whatever to the labeling of physicians' prescriptions by the pharmacist.

The same is true of the paragraph, page 3, line 17, (k) beginning with line 17. This paragraph likewise does not exempt specifically in any way labeling of physicians' prescriptions; it is inadequate and indefinite; physicians usually do not desire their patients to know what is administered; it is not necessary and will be most difficult to carry out as the containers are small and do not give much room for other than specific directions.

While the above two sections seem to exempt the practitioners of any branch of the medical profession, the practice of which is licensed by law, they refer only and specifically to "medical opinion", and does not in any way refer or exempt the provisions contained in section 402, (d), page 16, and (f), page 17, misbranding of drugs.

Not going into detail, we respectfully call your attention to the fact that if this bill becomes a law as it is now written, if a prescription contains, under (d), "Alpha eucane, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphonmethane, or any habit-forming narcotic or hypnotic substance and a statement, "Warning—May be habit forming", must appear on each prescription, bottle, powder box, or ointment jar, if the above-named ingredients are prescribed.

(e) Part of this section under (2) reads as follows: "In case it is fabricated from two or more ingredients the name of each active ingredient." This means that the formula for each prescription will have to appear on the label. Then if (1) under (f) requires "complete and adequate directions for use", this would eliminate the privilege of using as directed or three times a day. It is quite obvious that inasmuch as directions must be continually changed, depending upon the condition of the patient, it would be impossible to comply with this requirement.

The second part of (f) demands that warnings be placed on the label of medicines when they might be objectionable on account of pathological conditions or when used by children. I submit that if the physician fails to carry out this provision it would be impossible for the pharmacist to do so, as he is not aware of these conditions. The result would be that the prescription could not be compounded until the pharmacist was able to consult the physician and hours may elapse before the physician could be located and his patient necessarily would suffer.

The present law requires that certain narcotics be placed on the label when prescribed and the Federal officials have never required labels to be so written. This was due to a ruling by Dr. Wiley, who held that it was never the intention that physicians' prescriptions should be so labeled. We take it at this time that the pure food and drug law, if enacted, will be enforced and it is our understanding that Mr. Campbell has so indicated. Now is the time to correct both the present law and to correct any law that will change the present law so that the practice of medicine and pharmacy will not be unfairly interfered with. Further, as the Pure Food and Drugs Act covers shipments in interstate commerce, the District of Columbia and the Territories, these burdens will be placed on physicians' prescriptions in the District of Columbia but will not apply to prescriptions filled in the 48 States. It must also be remembered that these requirements will also apply, if S. 5 becomes a law, to medicines dispensed by physicians as well as medicines filled on a doctor's order by pharmacists.

Without question, this legislation should carry, before it is enacted into a law, an amendment exempting physicians' prescriptions in the District of Columbia specifically from the labeling provisions. Such an amendment would not, in any way, change the requirements for the purity, identity, or strength of medicines purchased by physicians or dispensed by the pharmacist. In no way will such an amendment interfere with the protection of the public.

I submit that it must be obvious that if S. 5, as now written, becomes a law, the danger of self-medication will result due to the unnecessary information given on the label which might be most misleading, because we are aware that under certain conditions medicines act in one way, while under different conditions the same medicine, for the same patient, might act differently and, in fact, endanger health.

Our committe, speaking for the association which it legislatively represents, will very willingly cooperate with you in obtaining the desired changes in this important legislation.

Respectfully submitted.

SAMUEL L. HILTON, *Chairman.*
H. M. BRADBURY.
F. B. CAMPBELL.
M. G. GIBBS.
W. P. KENEALY.
W. B. PHILIP.

(Whereupon, at 5:35 p. m., an adjournment was taken until 9:30 a. m. of the following day, Saturday, Mar. 9, 1935.)

FOODS, DRUGS, AND COSMETICS

SATURDAY, MARCH 9, 1935

UNITED STATES SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to adjournment, in the caucus room, Senate Office Building, at 9:30 a. m., to further consider S. 5, Senator Gibson, acting chairman of the subcommittee, presiding.

Present: Senators Gibson (acting chairman) and Copeland.

Senator GIBSON. The committee will come to order.

The statement of Mr. Garard, professor of chemistry at Rutgers University, may be received in lieu of any other statement.

STATEMENT OF IRA D. GARARD, PROFESSOR OF CHEMISTRY AT RUTGERS UNIVERSITY

Mr. GARARD. Mr. Chairman and members of the committee, I am Ira D. Garard, professor of chemistry at Rutgers University. I have had an academic interest in the regulation of food and drugs for many years and have been concerned on numerous occasions with some practical aspects of the composition of food and cosmetics sold to the public and with the advertising of such products. I speak personally.

The proposed Senate bill (S. 5) is a considerable advance over the Food and Drugs Act of June 30, 1906, but I venture to offer for your consideration a few comments in the interest of clarity.

A definition of "package" should be included in chapter II. Section 2 (k) of S. 580 would seem to be a suitable definition.

The word "devices" as it occurs in section 201 (b), lines 11 and 13, should be retained instead of "appliances", which has been suggested. The term "device" would include diets, exercises, or other prescribed schemes for the improvement of health which are now advertised widely and some of which are undoubtedly worthless and in many cases fraudulent.

In section 302 (c), line 8, page 6, "type of equal size" is clearer than "type of uniform size."

In view of some of the testimony that has been offered before the committee, I should like to add a few comments on some other features of S. 5.

Advertising of foods, drugs, and cosmetics should be regulated by the Food and Drug Administration and not by the Federal Trade Commission. The former has a scientific staff and will be familiar with many advertised products because of its control of them in interstate commerce, thus saving a separate investigation for adver-

tising infringements. Its point of view is primarily the welfare of the public health, while that of the Federal Trade Commission is primarily economic.

In brief, an advertisement is essentially an extension of the label and should be regulated by the same body that regulates statements on the label. The word "fraudulent" should not get into this section because it will be practically impossible to prove fraudulent intent in advertising.

The apparent reason for the specific inclusion of germicides and antiseptics (section 402 (j) and (k)), and not all classes of drugs is the fact that they are sold widely to the public for self-medication. This may be sufficient reason. If so, it seems to me that there should be a distinction between germicide, bactericide, and disinfectant on the one hand and antiseptic on the other. Dictionary definitions reflect previous usage and do not necessarily indicate proper usage. There are certainly many substances that have a high degree of usefulness as antiseptics but are not germicides. One such product that has come to my attention shows low germicidal action but is used widely by physicians, who claim it to be very effective. The few known substances that are effective germicides cannot always be used in contact with infected parts of the body because of their caustic or irritating nature, and so the availability of milder antiseptics may be very important. Competent information should be secured from bacteriologists as to what antiseptics would still be permissible under the present wording of the bill. I am inclined to believe that many of those now widely used in hospitals would be eliminated.

In view of the fact that section 703 provides for committees on public health and food standards and for hearings by the secretary, an advisory committee seems unnecessary. Therefore, section 704 could be omitted.

Senator GIBSON. Is Mr. Matthews here?

(No response.)

Senator GIBSON. Is Mr. C. L. Fardwell present?

(No response.)

Senator GIBSON. Mr. C. H. Jones?

(No response.)

Senator GIBSON. Mr. William Y. Preyer?

Mr. WILLIAM Y. PREYER. I will file a brief, Mr. Chairman, if you please.

Senator GIBSON. You desire to file a brief?

Mr. PREYER. Yes; I desire to file a brief.

Senator GIBSON. Mr. W. Bruce Philip?

(No response.)

Senator GIBSON. Mr. Harry Noonan?

(No response.)

Senator GIBSON. Mr. Herman L. Hoops.

STATEMENT OF HERMAN L. HOOPS, REPRESENTING HAWLEY & HOOPS AND 21 CONFECTIONERIES

Mr. HOOPS. Mr. Chairman and members of the committee, my name is Herman L. Hoops. I am a member of the firm of Hawley & Hoops, confectionery manufacturers, of New York City, which

firm has been in existence for 60 years. I represent 21 confectionery manufacturers, who are: American Candy Co., Milwaukee, Wis.; Paul F. Beich Co., Chicago, Ill.; Bunte Bros., Chicago, Ill.; Butter Cream Confectionery Corporation, Union City, N. J.; Bradley-Smith Co., New Haven, Conn.; Catawba Candy Co., Sandusky, Ohio; Goelitz Confectionery, North Chicago, Ill.; Hawley & Hoops, New York, N. Y.; Robert Johnson Co., Milwaukee, Wis.; Lewis Bros., Newark, N. J.; Maillard, Long Island City, N. Y.; Ed Messer Confectionery Co., Cincinnati, Ohio; Metro Chocolate Co., Brooklyn, N. Y.; National Candy Co., St. Louis, Mo.; New England Confectionery Co., Cambridge, Mass.; Reymer & Bros., Inc., Pittsburgh, Pa.; Rockwood & Co., Brooklyn, N. Y.; Runkel Bros., Inc., New York, N. Y.; Frank G. Shattuck Co., New York, N. Y.; Ph. Wunderle, Philadelphia, Pa.; and George Ziegler Co., Milwaukee, Wis.

Before I present my brief statement on resinous glaze I should like to present a few samples coated with this material and also some pieces of the gum lac in its natural state as used by confectioners. You will also find some twigs with buds of the horse-chestnut tree, which will illustrate the use of resinous glaze by nature in protecting these winter buds against snow and rain.

These firms which I am here representing represent an investment of many millions of dollars and also employ many thousands of men and women.

On behalf of these 21 leading manufacturers of confectionery we ask the elimination from section 301, paragraph (4), line 17, committee print no. 3, S. 5, the words "resinous glaze."

This substance is now and for more than 50 years has been in general use by manufacturers of confectionery, both in this country and abroad.

It serves an important and useful function in the manufacture of certain types of confectionery, such as chocolate-covered peanuts, raisins, almonds, and other similar products known in the trade as "chocolate-panned goods", also decorettes, fudge, marzipans, chocolate candy, butter creams, dairy creams, candy corn, and other varieties.

Contrary to the popular conception, resinous glaze contains no rosin. It is a vegetable gum resin which forms on trees. It contains ingredients of recognized food value, such as exist in olive oil and butter. It is not to be confused with shellac, the product commonly used in the paint trade for industrial purposes. The glaze used by confectioners is purified and free from all deleterious substances and is guaranteed by the glaze manufacturers to conform to the Federal Food and Drugs Act. It is commonly known as "lac."

Confectioners are confronted with the problem both of preserving natural moisture in their products and of protecting them from the absorption of moisture and contamination from outside sources. This is the primary reason for the use of lac and, if confectioners are deprived of the use of it, it means a loss of volume to the industry as a whole of several million pounds of confectionery, for which there is now a ready and substantial market.

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This substance is now and for more than 50 years has been in general use by manufacturers of confectionery, both in this country and abroad.

It serves an important and useful function in the manufacture of certain types of confectionery, such as chocolate-covered peanuts, raisins, almonds, and other similar products known in the trade as "chocolate-panned goods", also decorettes, fudge, marzipans, chocolate candy, butter creams, dairy creams, candy corn, and other varieties.

Contrary to the popular conception, resinous glaze contains no rosin. It is a vegetable gum resin which forms on trees. It contains ingredients of recognized food value, such as exist in olive oil and butter. It is not to be confused with shellac, the product commonly used in the paint trade for industrial purposes. The glaze used by confectioners is purified and free from all deleterious substances and is guaranteed by the glaze manufacturers to conform to the Federal Food and Drugs Act. It is commonly known as "lac."

Confectioners are confronted with the problem both of preserving natural moisture in their products and of protecting them from the absorption of moisture and contamination from outside sources. This is the primary reason for the use of lac and, if confectioners are deprived of the use of it, it means a loss of volume to the industry as a whole of several million pounds of confectionery, for which there is now a ready and substantial market.

In the early days of the administration of the present Food and Drugs Act, objection was raised to the use of lac on the ground that it concealed inferiority. This is a false premise, because the confectionery upon which lac is used are made from approved ingredients and are of excellent quality. Upon this being demonstrated in court proceedings, the use of lac for the purpose indicated has been permitted for more than 20 years without any proceeding being instituted against it by any State or Federal food law officials.

The use of lac by confectioners has been made a subject of extensive study by Dr. A. C. Langmuir of New York City. We quote from his report as follows:

The confectioner uses lac glaze in the same way that nature uses a resinous coating to protect the grains of barley, wheat, and other cereals. These resinous coatings are impervious to moisture and the beneficial effect is due to the fact that they conserve the moisture within the seed or food product and prevent the access of excessive moisture from the outside in humid weather which would spoil or destroy the appearance and palatability of the candy or grains.

In precisely a similar manner the honey bee, which gathers honey from the nectar of the flowers just as the lac insect obtains the resin from the sap of certain trees, deposits its honey in a framework of wax and seals the cells with a resin which prevents the crystallization of the honey in dry weather and the liquifying of the honey in wet weather. The confectioner by using lac seeks to attain in an equally harmless way the object of rendering and keeping his product suitable for consumption.

Plant cells always contain, in addition to starch, protein, and fat, a portion of resin, and in some food products, such as ginger, cloves, and pepper there are large amounts of resin. Vanila extract contains up to 8 or 9 percent of resin and the Government requires that this natural resin be present when the extract is sold.

Lac is the only resin similar in its origin to honey and which has been shown to resemble the food fats in its composition. In fact, it is classified by chemists as a "fatty" resin because it contains in itself ingredients of food value common to foodstuffs such as butter and olive oil.

Although extensive investigations have been conducted by chemists extending over a long period of years, no acceptable substitute for lac which can be used in the confectionery industry has been discovered. In addition to preserving the freshness of the confections, lac serves to protect confectionery from contamination to which soft bulk candy is subject when displayed in many stores, as much of it is displayed, without protection from flies, dirt, and mold. The confectionery in connection with which lac is used is prepared under the most modern sanitary conditions. The confectionery is wholesome, labeled to show it is coated with lac, and the lac does not in any way contribute to the deception of the public.

It is submitted, in view of the fact that resins commonly occur in a variety of other articles of food, that there is no good reason for barring the use of resinous glaze in confectionery.

Lac softens at the temperature of the body and passes through the acid stomach juices unchanged, but is entirely dissolved and assimilated in the upper part of the intestine which is drenched with strongly alkaline fluids. These fluids rapidly act on lac. Lac can in no sense be termed an inert material. It neither disturbs nor impairs digestion. It is neutralized in the body, some 70 percent of it being added to the body's food supply.

The amount used by confectioners is extremely small. The thin film of lac remaining on the candy after the evaporation of the grain alcohol, amounts to less than one-third of 1 percent by weight.

Dr. Langmuir, from whose report we have quoted, is the author of many papers on the chemistry of resins and lac. He has represented the United States both in London and Calcutta in drawing up international methods for the standardization and purity of lac and its products.

Inasmuch as the use of lac has been thoroughly investigated by Dr. Langmuir and it has been demonstrated that its use in confectionery is neither deleterious nor harmful, but contains wholesome ingredients of demonstrated food value, and since its use is essential for the manufacture and proper merchandising of certain types of candy, it is believed that there are no good grounds for striking down a large volume of the products of the candy manufacturing industry by prohibiting, as Committee Print No. 3 does prohibit, the use in confectionery of resinous glaze.

Dr. Langmuir states that under this bill resinous glazes of any character are prohibited. This would apply not only to lac but also to resins contained in food products such as vanilla extract or honey in the comb. Resinous glazes could be prepared from both of these foods but under this bill their use or the use of any other harmless resins which may be later discovered would not be permitted. Vanilla extract, containing 5 to 10 percent of resins may be added in any amount to candy but its use on the exterior would be prohibited because it would constitute a resinous glaze.

We request, therefore, that the words "resinous glaze" be stricken out where they appear in line 17, paragraph (d) of section 301, Committee Print No. 3, S. 5.

Dr. Langmuir, who is an authority on lac and resinous glaze, is in this room and I should like to ask him to make a brief statement. He would be glad to answer any questions you may care to ask.

Senator COPELAND. Did you appear last year, Mr. Hoops? I have forgotten.

Mr. HOOPS. No; I did not.

Senator COPELAND. How does it happen that you made no appearance before?

Mr. HOOPS. We did not know of this before.

Senator COPELAND. What was that?

Mr. HOOPS. We did not know of this before because Dr. Stroud Jordan apparently conceded that resinous lac seems to be objectionable and we object to his ideas on that subject.

Senator COPELAND. You do not agree with the doctor?

Mr. HOOPS. I do not agree with him, and neither do these other 21 firms.

Senator COPELAND. I noticed at the beginning of your statement that among the samples presented are some horse-chestnut buds. Is the glaze that appears naturally on the horse-chestnut buds the same material that you use in your candy?

Mr. HOOPS. I would prefer to have Dr. Langmuir answer that. I think he is more familiar with that subject.

Senator COPELAND. Perhaps he will answer it now.

STATEMENT OF DR. A. C. LANGMUIR, REPRESENTING HAWLEY & HOOPS

Dr. LANGMUIR. I am the gentleman to whom Mr. Hoops has referred. I am a chemist with some 20 years' experience in the chemistry and manufacture of confectionery glazes, and I am not now connected with either confectioners or manufacturers of glazes. I am retired.

I want to say primarily with respect to the question Senator Copeland has asked that resins are a class of substances contained in foods and vegetables just as protein, starch, fats, and sugars are contained. It is a normal constituent of the plant cell. It exists in vegetables and foods, and when we eat vegetables and foods we consume quantities of resin.

When we use certain foods like ginger, cloves, pepper, and vanilla extract we eat large quantities of resin.

Nature has the same problem as the confectioner. Here is a sample which everyone knows is honey in the comb. Now, the bee is an insect just like the lac insect. The lac insect metamorphoses the sap of the Kasum tree in India. The honey bee takes the nectar from the flowers and converts the nectar into beeswax, which it uses to store fluid honey. It then fills those wax cells with honey itself, and then it is necessary to seal those cells, which are hexagonal in shape, with some resinous material which is thin and easily punctured, and which at the same time will protect this honey from crystallization in dry weather and liquefying in wet weather. It preserves the honey of the bee. That is what the confectioner wants to put on his candy to keep it from drying out in dry weather and to keep it from becoming soggy in wet weather.

Answering the Senator's question as to the horse-chestnut bud, I got that yesterday in Washington. If you cut those buds open you will find they are packed full of leaves and flowers, which will develop as soon as the sun strikes them in the spring. The horse chestnut bud has the problem of carrying those leaves through the winter against storms and ice. It does it by putting on a resinous glaze, which serves its purpose. That resinous glaze you will notice is quite sticky. If it were not sticky, it could be dissolved in alcohol and used as a resinous glaze on candy. The confectioners could not use that. The confectioners use that material of which you have a sample which looks like the gum on a cherry tree. Confectioners use that material which is produced by the insect and is ground, purified, and dissolved in alcohol. A characteristic of all resins of the nature of this and others is that a resin is soluble in alcohol and impervious to and insoluble in water. That is why it is valuable and is used by nature on cereals and other things.

Senator COPELAND. I think I had this conception of the origin of this substance: This is not secreted by the fly as the product is you mentioned in connection with the operation of the bee. Is this not a scale from the fly?

Dr. LANGMUIR. No; in no sense of the word.

Senator COPELAND. Now, tell us about it.

Dr. LANGMUIR. Why, the lac insect punctures the bark of certain trees in India. I have been in India myself. It punctures the bark of these trees and these delicate twigs, and you will notice all those

are small, and it takes small twigs because they contain an abundance of sap, and the lac insect converts that sap into this resin just exactly as the honeybee converts nectar into honey and into beeswax. The lac insect uses it for the same purpose, to protect the eggs, and later on the eggs hatch and the insect flies away, and we get the lac resin, wash it, pulverize it, and eliminate all the impurities. This resin is just the resinous glaze these insects use. It is a product of the metabolism of the insect, and the insect not only makes the resin but in it it includes a certain amount of gluten, a certain amount of sugar, and a certain amount of coloring matter. It is a complex mixture.

Senator COPELAND. If you were to take this substance as it is when it comes from the twig, does it contain any substance which would be harmful?

Dr. LANGMUIR. None whatever. It has been tested—probably more thoroughly tested—by scientists than any other resin. I do not know of any resin which has been tested as much as that has.

I want to say that in 1911 Dr. Wiley, who was then the head of the Bureau of Chemistry, conceived the idea this resin was inert and, therefore, possibly a dangerous material to use on candies. He thought it went into the body unchanged, and he brought a number of cases against the confectioners, and I, as a manufacturer of these glazes and also as a chemist, testified for the confectioners of the trade.

Some six cases were brought between 1911 and 1916, and in one of those cases at Baltimore Dr. Wiley himself testified for the Government. And in not one of those cases was the Government able to show to the judge or jury that there was anything harmful or deleterious about lac. And after having lost six cases they abandoned any court proceedings and permitted the free use of lac from that time until the present. It has been used now without any question from the Government and without any criticism by court action for over 20 years, and has been used all over the United States.

Senator COPELAND. I would like to ask you this: The frequent criticism against the use of this substance is that this is really shellac.

Dr. LANGMUIR. I would like to answer that question.

Senator COPELAND. I would like to have you answer it.

Dr. LANGMUIR. It is no more shellac than flour is wheat.

Senator COPELAND. You have heard the criticism, have you not?

Dr. LANGMUIR. I have heard that, and that is a legitimate criticism up until the time the new product was made by me. I originated the new product in 1911, using this particular material in your hand as raw material. Long before, in the paint trade, this had been converted into a shell-like form shellac. And that was satisfactory. You take that stuff up there [indicating] and you grind it up and you may mix it with rosin or you may do anything with it, just as flour starts with wheat, you may do anything with the flour. You cannot interfere with the wheat, however. They take this material and manipulate it anyway they may desire, and mix it with anything they wish to. They may add any sort of coloring matter that may be used on a floor, which, of course, does no harm. That was the original idea. I think what lies back of this whole thing to-

day by the Department is that they subconsciously feel a prejudice against this lac because they associate it in their minds with shellac used by the paint trade. I think that is entirely wrong and erroneous, and it has not been true for 25 years.

The bill here goes further than that, though. It prohibits the use of any resinous glaze, page 5, line 17, where "any resinous glaze is prohibited." I, as a chemist, believe that I could get in touch with the manufacturers of beeswax, the people who prepare the honey from the comb and obtain beeswax, and could develop processes for extracting the particular resin which is used by the bee in sealing those cells. If I dissolved that resin in alcohol and submitted it to Mr. Hoops as resin glaze on candy, he would not be permitted under the law to use that, because that is undoubtedly a resin glaze, and all resin glazes are prohibited. In the case of vanilla extract, alcohol is used on the vanilla bean in order to extract the vanilla extract. Incidentally, it extracts resin to the extent of about 5 percent. Mr. Hoops would be allowed to add to his candy vanilla extract in any amount provided he did not increase the alcohol over one-half of 1 percent but he could not pour that extract over the outside of the candy because then it would be a resinous glaze.

This particular resin used by confectioners is not harmful or deleterious, and it is what is known as a "fatty resin." It is entirely harmless. And I ask that this term "resinous glaze" be removed from the bill.

Senator COPELAND. Are you familiar with candy making?

Dr. LANGMUIR. I have only seen it incidentally. I have never made it myself.

Senator COPELAND. Mr. Hoops, suppose I ask you, if the chairman will permit it, is there any substitution for this?

Mr. HOOPS. No known substitute, Senator.

Senator COPELAND. Why do you use it outside of the fact that you keep your product fresh inside and so forth? Does it prevent the pieces of candy from sticking together, too?

Mr. HOOPS. Yes, sir; in humid weather. And also it prevents drying out the moisture of the candy.

Senator COPELAND. Are all the candies we see that are glossy as these are coated with this same substance?

Mr. HOOPS. Not at all.

Senator COPELAND. What other method is used of coating them to give them this glaze besides the use of lac?

Mr. HOOPS. Some methods are used where they use the mineral oil and wax. That is limited to applying it to pieces which are round or egg shaped.

Senator COPELAND. Are those substances that you have just mentioned in the making of other candies, do they preserve them and keep them from sticking together and so forth the same as lac?

Mr. HOOPS. They have the same effect. But they cannot be applied to all pieces.

Senator COPELAND. I was diverted for a moment. You say it is a mixture of mineral oil and what?

Mr. HOOPS. Wax.

Senator GIBSON. Beeswax.

Senator COPELAND. What sort of wax?

Mr. HOOPS. Beeswax or something of that kind.

Senator COPELAND. May I turn to the chemist again? When they use that wax are they using a substance which is very similar to lac?

Dr. LANGMUIR. No; this beeswax is entirely different and foreign to resin. In a wax you have a substance known as "cetyl alcohol." There is a vast difference between wax and resins or wax and fats. I should say myself that beeswax was an entirely indigestible substance and goes through the body absolutely unchanged. Whereas, this lac resin here has a large proportion of fatty acids combined with it and is softened in the body. It is not attacked by the acids of the stomach. It is attacked by the alkaline fluids in the upper portion of the intestines which are alkaline to the equivalent of 1 percent soda. That is what happens in the body. And to that extent it would be digestible because we know it contains fatty acids.

Senator COPELAND. Your contention is, I assume, that the lac used in this candy then has greater justification so far as nutritive value than beeswax?

Dr. LANGMUIR. Much more.

Senator COPELAND. Are you quite sure about that?

Dr. LANGMUIR. Quite sure. I am very sure.

Senator COPELAND. How would you make your candy, Mr. Hoops, if we said you could not use resinous glaze?

Mr. HOOPS. We would have to stop making it.

Senator COPELAND. That is the argument that we hear usually, you know, when we are trying to impose any new regulation. Is it really so that you could not make a candy then?

Mr. HOOPS. It is really so. On account of different shapes, and so forth, no other glaze could be applied.

Senator GIBSON. You mean you could not make this kind of candy?

Mr. HOOPS. No; we could not. And many other kinds could not be made.

Senator COPELAND. Is this one of your chief products?

Mr. HOOPS. Yes, sir. We sell a great deal of it.

Senator COPELAND. What proportion of your sales consist of this particular kind of candy?

Mr. HOOPS. I do not know, offhand, but I should say approximately one-third.

Senator COPELAND. Are you familiar with Dr. Jordan's work on candy?

Dr. LANGMUIR. I know Dr. Jordan, and I have talked with him, and I do not understand Dr. Jordan's attitude.

Senator COPELAND. Is Dr. Jordan still here?

Mr. HOOPS. He is not here that I know of.

Senator COPELAND. He criticizes the use of this, does he not?

Mr. HOOPS. He does.

Senator COPELAND. Did you say you talked to Dr. Jordan about it?

Dr. LANGMUIR. Not about this particular bill. I have talked with him in the past about other things. I would not say Mr. Jordan was particularly competent as a witness, although I have every respect for the man. I would not say that his knowledge of lac was profound.

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Senator COPELAND. Is yours?
Dr. LANGMUIR. Yes.
Senator COPELAND. All right.
Senator GIBSON. Is Mr. Gould here?
(No response.)
Senator GIBSON. Mr. Rosenthal?
(No response.)
Senator GIBSON. Mr. Swain?
(No response.)
Mr. W. P. JOHNSON. Mr. Chairman, while you are waiting for them may I file a brief?
Senator GIBSON. Mr. W. P. Johnson wishes to file a brief, and we accept your brief, sir.
Mr. JOHNSON. That is all I care to file.
Senator GIBSON. Mr. Swain?
(No response.)
Senator GIBSON. The next is Mr. Epstein, or maybe that may be somebody representing the Epstein Institute.
Senator COPELAND. That is the Institute of American Fat Oils.
Senator GIBSON. Mr. Fraser.

STATEMENT OF SAMUEL FRASER, REPRESENTING THE INTERNATIONAL APPLE ASSOCIATION

Mr. FRASER. My name is Samuel Fraser, representing the International Apple Association, of Rochester, N. Y.

Mr. Chairman, the International Apple Association, which I represent, consists of growers and distributors of apples and pears throughout the United States. In our membership we have the cooperative apple associations extending from the Pacific to the Atlantic coast.

Since the matter of spray residue and the manner of handling it is vital to this industry, 16 of the State horticultural societies of the East and those of the West are also working with us and the American Pomological Society on this problem.

In the case of fruits and vegetables we have about half of the farmers of the country more or less interested, somewhere about 3,000,000. And while, for instance, I myself as a grower am interested in apples I am perhaps to a larger extent interested in cherries. I am also interested in other crops, and until the last few years, was extensively interested in agriculture, handling up to 16,000 acres. So that I have more or less contact with the agricultural question.

I wish to point out for the benefit of the committee that taking the rail figures for 1923 to 1929 we loaded on rail about a pound a day per capita, 360 pounds a year, of fruits and vegetables. In other words, the public are getting about a pound a day by that route in interstate commerce, and about an equal amount moving by other means—trucks, and so forth.

The use of fruits and vegetables has grown very rapidly in the United States. Our movement is now four times what it was 40 years ago, although there is no like increase in population.

I think the committee have very well recognized, and we appreciate their attitude, the fact that the great fight by man for his food is with the insect life. Moses recognized it. For 3,000 years statesmen have recognized that the great conflict for food was between man and the insect world, and you have rightfully recognized the position in which we find ourselves.

I also wish to point out what I believe to be the function of a Government; it is essential that it protect a necessary minority. It is sound economics as well as an important factor in Government. The American farmer had about $14,600 each in 1920. In 1933 the data showed that we have left 25 percent of that capital, $3,720. The annual income per farm has been as high as $900, including the use of the house and the vegetables grown or foods grown, and in 1932 it was $231. In 1933 it was $481. The importance of bringing this to the attention of the committee is that this legislation places all liability on the grower. We have freed the distributor from the liability with regard to our commodities. Accordingly, the 3,000,000 growers are very vitally interested in this legislation. I feel that that is worthy of consideration, and I believe you have given it consideration.

Senator COPELAND. Just a minute, Mr. Fraser.

Mr. FRASER. I think you have given it consideration. I recognize it and we appreciate it.

Senator COPELAND. I hope during your testimony that you will make any defense you care to make about the use of sprays, and answer the charge made that spray residue is responsible for a great many human ailments, and that the consumer is not properly protected as he should be. I do not want to change your line of thought, but I want to hear about that.

Mr. FRASER. If I may take just one moment I will return to that. And I wish you would bring me back to it.

Fruits and vegetables are the great cash crop of the American farmer. In the last 2 years the income from fruits and vegetables, which has amounted to $1,245,000,000, exceeds the income from all grains—wheat, oats, rye, barley, corn, rice, and all cotton products combined. In other words, especially with the changes now taking place in American agriculture fruits and vegetables are becoming of a greater importance to American agriculture than ever before. I believe these facts and the fact that no nation is situated as well as the United States, no nation has such an array of fruits and vegetables in its diet, and perhaps no nation is as well taken care of in its regulations and in their enforcement as is the United States, and no nation, for instance, has any tolerance on lead. No nation has any lower tolerance on arsenic. And I wish to make it clear that our association has endorsed the maintenance of these, although there is no law under which the Secretary of Agriculture could make a tolerance. But the industry has put itself under a tolerance for the purpose of guidance and to assure the public that all is being done that should be done.

Senator COPELAND. I wonder, Mr. Fraser, if you made clear exactly what you meant when you said there was no nation which makes tolerance on lead. Did you mean no other nation?

Mr. FRASER. No other nation; I should have said that, no other nation. So to that extent I think the food and drug administration is to be commended for the manner in which it is safeguarding the American public. And I am submitting and I have brought with

me a written statement in which Mr. Phillips joins expressing the association's attitude.

Senator GIBSON. Do you wish to file that?

Mr. FRASER. No. I just want to read this preface on this point only.

> We wish to again emphatically state and to make plain beyond a shadow of a doubt, as we have in previous statements during the progress of this measure from its inception as S. 1944, that no industry has given greater or more constructive support to pure-food laws and to the Federal Food and Drugs Administration than the apple and pear industries. That support still continues, but it does not mean that any industry or any citizen is under obligation to accept without constructive criticism and suggestion any and all proposals that may be advanced.
>
> All we have been or now are interested in is to secure a proper law.
>
> The bill, as it stands, is superior to its predecessors.

Senator COPELAND. Mr. Fraser, let me ask you there, is it more favorable because it is less protective to the public?

Mr. FRASER. Oh, no. I do not regard it in that sense at all. I only mean in the proper attitude to its citizens on both sides; it is much more workable and much more in line with our conception of justice.

Senator COPELAND. That may be, but the question is, as we have evolved this present bill, have we done so by lessening consumer protection?

Mr. FRASER. I do not think so.

Senator COPELAND. What do you mean, that it is a more favorable bill?

Mr. FRASER. If a piece of legislation is such that it brings righteous indignation on the part of those on whom it is to operate, instead of bringing them into cordial support, it has not been presented in its proper attitude.

Senator COPELAND. I do not think that is quite a complete answer. Have we by changes made in this bill let down the bars and given less protection to the consumer? This is a health measure. We do not want to impose burdens upon producers or manufacturers, but are we doing things here to render this bill less protective of the citizen who consumes the articles, for example, that you produce?

Mr. FRASER. I do not think so.

Senator COPELAND. Tell us why; why you feel so. Are we making it possible to evade our responsibility as regards protection against spray residue? Are we doing things that would make it possible to sell in interstate commerce articles that are produced and when consumed by the citizen do him harm?

Mr. FRASER. Not at all.

Senator COPELAND. I would like to have you enlarge upon it so far as I am concerned, Mr. Chairman, if you will permit me to follow the thought?

Senator GIBSON. Yes.

Mr. FRASER. I would only like for a moment just to outline how far we have gone under the present law, taking my own apples. We have no tolerance in law today.

Senator COPELAND. We have no what?

Mr. FRASER. We have no tolerance in law today. But the industry established one, and we have worked with the Department in developing a consciousness on the part of growers to recognize

that as a right procedure. You are going to give the Secretary the right to make a tolerance, which once it is violated means that he need not go any further than to prove that the person violating this provision is guilty of an infraction of the law. Today the Department must prove its case from the ground up that that particular alleged violation is detrimental to health. Now, you are removing from the responsibility of the Department that particular requirement and allowing them to establish a tolerance, and all they will need to show is that that particular lot of apples, or any other thing, has more than the tolerance provides.

Senator COPELAND. You are not antagonistic to that?

Mr. FRASER. Oh, we have developed it. Furthermore, I think some of the toxicologists with whom we have discussed these problems of tolerances, will agree that the tolerance established for arsenic is so far below the point at which it might have been placed that we have practically leaned over backward in safeguarding the public, and before a court of review it might be possible to secure a ruling for a tolerance twice that which we now have. The industry has aided in maintenance of the present tolerance which we regard as safe for the old and young and sick and well, and meets the full requirements of the Supreme Court. Now we are writing that into law, the power for the Secretary to promulgate a tolerance.

Senator COPELAND. I am not so much interested in what the Supreme Court said as I am that the citizen is protected in his or her health.

Mr. FRASER. I think you have gone as far as you can. I do not see what more you could do. The health of the consumer is fully protected and has been under the present law. Our amendments are directed at phases of this bill that in no way affect the health of the consumer.

Senator COPELAND. Do you think this bill is so written that the Food and Drugs Administration have power to establish tolerances that will guarantee safety to the consumer?

Mr. FRASER. I do.

Senator COPELAND. I wish you would put in the record, if you will, why it is necessary to use these sprays and so forth.

Mr. FRASER. Because at the present time we know of no other way of controlling the insects so that we may produce the crop.

Senator COPELAND. I remember when I was a boy that I would go out to my grandfather's orchard and we had fine apples there. Perhaps it was because I was a boy and would eat anything, but my recollection is the natural product at that time was a very superior article contrasted with the natural product today. Is that true? Has there been progress in the last 50 years in the growth of pests and an increasing menace to food products?

Mr. FRASER. They are increasing all of the time, and our cost of fighting them is growing from year to year.

Senator COPELAND. Have we imported a lot of those pests?

Mr. FRASER. Some. Some have turned from one food to another.

Senator COPELAND. Why; because the first food is no longer cultivated?

Mr. FRASER. They have shown adaptability. In some cases, we have brought them in. The codling moth, for instance, was brought in sometime in the eighteenth century, but it is domesticated now.

That is one of the things we have to spray for. It is the same way with other insects; they have either turned to living on our fruits or they have been brought in, so we have to fight them.

Senator COPELAND. What would be the effect upon apple production, for example, if you were to stop from this time on any spraying, or do you know?

Mr. FRASER. I would go out of business.

Senator COPELAND. I know you would go out of business, but what would happen to the orchards? Would they go out of business, too?

Mr. FRASER. The trees might stay for a time and after a fashion. You would not get many apples because the insects would exert their monopolistic attitude and practically eat the crop. Production would be practically ruined.

Senator COPELAND. Then you have to have some system of control, as we have to have in government to keep these great interests from taking control.

Mr. FRASER. We have to.

Senator COPELAND. But for the sake of the record, because this is a matter discussed by the public, and you see lots of articles in popular journals on the subject——

Mr. FRASER. May I just show you what I am today doing with my crop? This year was very dry. We were so short of water that we have been hauling water until the last 6 weeks. I could not get water to operate except by hauling it 3 miles. I dusted my fruit to save hauling water with which to spray. That is I blew dust powder on the trees. This was done 13 times during 6 months growing season and in nine of these we used dust containing an arsenical compound. I harvested what apples I could when they made 2½ inches diameter and hauled them to storage 30 miles away, because there was a washer there and water. I harvested the crop entirely when the season came to a close and took them off down to less than 2 inches diameter and they were hauled 30 miles and placed in a storage where there is water in case I need it. We submitted apples for analysis, and we pay for the analysis if we desire a certificate. We found that they would meet the tolerance, so we proceeded to sell them. If they do not meet the tolerance the State authorities go through our storages in western New York and take samples, and when you go to move your apples, you find a red tag on them. Now, a red tag means that you cannot move those apples out of that storage until they have been brought into compliance with the law.

Senator COPELAND. How is that done?

Mr. FRASER. That may mean they must be washed. And the washing may consist of two operations. If the amount of residue is large they may be put through an alkali bath as sodium silicate, and if there is a lot of wax on the apple the water may have to be heated up to 110° F. They are passed through that bath, rinsed, and then passed through a bath containing weak hydrochloric acid and rinsed with clean water and dried so that they are brought to a point that they have very little arsenic, other than the constituent arsenic, for apples, like some other commodities, may have constituent arsenic, and that is there just as it is in dandelion roots, or fish, or some of these other foods. So far as added poisons are concerned,

the apples and pears must meet the requirements of the law and then they will be allowed to be sold and to be moved.

Apples and pears were never as clean and healthful as they are today. They are freed of dust, dirt, spray residue, and placed in an excellent sanitary condition before being offered for sale.

Senator COPELAND. Is the law of New York more advanced than that of any of these other States?

Mr. FRASER. I doubt it. All States, municipalities, and even towns and villages have their general health laws.

Senator COPELAND. If this pending bill is passed would it guarantee that in interstate commerce the apples would be as safe for consumption as the New York apples are?

Mr. FRASER. Yes; of course. Let me just state the record. Last year, according to Mr. Campbell, 20 percent of the total Food and Drug Administration funds of $1,185,000 was used on fruit. They took 4,605 suspicious samples. They made 50 seizures of fruits. The number of apple seizures in 1933 was 137. In 1934 it was 34—a reduction of 75 percent. Total expenditure for fruits and vegetables in 1934 was $379,200 and there were 58 seizures.

Senator COPELAND. With the same degree of inspection and the same expenditure of money? You mean to say there was not any let-up in the inspection?

Mr. FRASER. No; we have had a great deal more interest manifest by the States. This does not represent the total sum of money used in these years. The various States are active in this program.

Senator COPELAND. We would like to be assured that there has been no let-down on the part of the Department.

Mr. FRASER. Not any.

Senator COPELAND. The activity is steady?

Mr. FRASER. It is increasing.

Senator COPELAND. But the seizures were lessened because of the efforts made by the industry itself to give clean and safe fruit?

Mr. FRASER. Yes. The number of effective washing equipments installed in the important producing areas has continued to increase, and the industry and the State authorities have set up effective and comprehensive methods of spray residue control. It is rapidly being recognized all through the commercial field, that we must in our own interest put our commodity above question.

Senator COPELAND. Have you gone to the extent of doing that, so that the United States now leads in the safety of its fruit, so far as this evil is concerned?

Mr. FRASER. It is equal to any, and above most.

Senator COPELAND. What other progressive countries are there in this respect?

Mr. FRASER. Well, we have met the findings on arsenic of Great Britain, in the case of the Royal Commission headed by Lord Kelvin in 1903, where they had a very exhaustive study of the whole problem of arsenic, and we have now accepted the findings of that commission in regard to that particular element.

Senator COPELAND. So the result of that work in England was to practically guarantee the safety of the citizen in consuming the fruit.

Mr. FRASER. Absolutely.

Senator COPELAND. And you say so far as we are concerned now in this country, that our standard is equally high.

Mr. FRASER. Yes. I do not think it should go any further, because it is about one part in a million being actually one in 700,000. One to a million is so infinitesimal, it is almost at the point that you begin to question your analysis. You can question it to a degree in there, but you are getting it fine enough.

Senator COPELAND. Now, Mr. Fraser, perhaps you could not qualify as an expert in this, but you would with me. Have you followed any cases where there was alleged poisoning from the use of fruits having spray residue?

Mr. FRASER. I have not seen a case.

Senator COPELAND. Have you heard of cases?

Mr. FRASER. I have heard of them, but I have not been able to follow one.

Senator COPELAND. Have you tried to follow them?

Mr. FRASER. I have tried to get all of the records we could. We have heard of two or three. We have not heard of one—not one in the last year—but we have not been able to put our finger on a definite case which was due to that cause.

Senator COPELAND. Have you heard of any in New York State?

Mr. FRASER. Not one.

Senator COPELAND. I remember a case we had one time in New York when cucumber pickles were found to contain arsenic, but when it was followed out by the health authorities it was found that the cask or the barrel in which they were stored had had some arsenic product in it. But I would like to be sure; and I hope the Department will furnish us with any information it may have on this subject, because it is our duty in writing this bill to make sure that the public is protected so far as we can write into law such protection.

Mr. FRASER. The case in Fairport, N. Y., this last year, where two children were alleged to have died from the stray residue on the fruit turned out to be carbon-monoxide poisoning of the stove. We followed that down to see, but the fact was that two of the four children were in the hospital recovering and two died because of the carbon monoxide. It was put on the Associated Press as a spray-residue proposition, but it was carbon monoxide. It was poisoning all right, but it was not spray-residue poisoning.

Time and again there have been scare headlines as to injury from residue which on investigation were found to be utterly without foundation and due to other causes. There was no basis for the claim that spray residue was involved.

Senator COPELAND. I am frank to say for myself, as one who is very much interested in public health, that this record should show it if we can find it.

Mr. FRASER. We would be glad to have it show it, but our attitude has been that we are putting out commodities so that they meet the most rigid, the highest standard of requirement to assure the public that there will be no question on the ground of spray residue.

Senator COPELAND. And you are not now discussing legal standards—you are talking about human standards.

Mr. FRASER. Absolutely. Just as near as we can make them, but we will have to recognize constituents.

Senator COPELAND. You mean the normal constituent?

Mr. FRASER. Those that are built into the plant from the soil. We have to recognize that.

Senator COPELAND. We cannot very well do anything about that by law.

Mr. FRASER. Oh, no. For instance, a baby when it is born shows a high arsenic content of the viscera, like any water animal. The codfish when it is caught while it is feeding in deep water shows four times as much arsenic in the liver as when it is feeding in shallow water. Cod-liver oil which we feed to the baby, and which is so valuable may show as high as 3 to 4 times the arsenic tolerance we are allowed to have on an apple, and it is very desirable for the baby (20 samples cod-liver oil showed arsenic ranging from 1.4 to 5.1 parts per million. See Industrial & Engineering Chemistry, May 1934, p. 573).

Senator COPELAND. Is that statement you have just made a well-authenticated statement?

Mr. FRASER. Yes, sure. Certainly. You eat fish which may contain from 7 to 12 times as much as we are allowed now to have on an apple, but it is constituent. Shrimps and prawn show 30 parts per million. We use the word "arsenic" without discrimination as to its form of combination. Toxicity varies with the form of combination. There may be some forms of combination as found in dandelion roots, lima beans, and so forth, in which the arsenic is eaten quite freely. The children gather the dandelions in the spring and eat them. Arsenic is normal to the plant and is constituent. A certain quantity of a food is good for a person, but its excess might not be. Fire is a splendid servant but a bad master, and it is the same with every other thing that we have to deal with in life.

Senator COPELAND. Is the industry making a constant study of new sprays and new substances to find one that is harmless absolutely?

Mr. FRASER. We are spending millions on it, and we are urging the Department to do so and we have aided in every way possible to get away from the use of arsenic.

Senator COPELAND. Is the Government spending as much money as it should on research in this field?

Mr. FRASER. We would like them to have more for research, especially in this line.

Senator COPELAND. Is there some research going on in the Government departments?

Mr. FRASER. There is a departmental committee in charge, since this is a composite question, and it has to be handled jointly by chemistry, etymology, and the regulatory department. Hence, some years ago we urged the establishment of a departmental committee so that no department would feel that its toes were trodden on.

Senator COPELAND (interposing). You mean an interdepartmental committee?

Mr. FRASER. An interbureau committee in the Department, so that the work might proceed and we would get somewhere. After nearly 10 years of work, we do not yet have a substitute equal to arsenate of lead for killing, and we have to fight harder now than ever, because the insects have shown a degree of adaptability to it. Every individual that is left as a hand-over and can stand that spray prop-

agates offspring that can stand that strength of dose, so that the Colorado codling moths, where the insect is most vigorous and where doses of arsenic have been increased without wiping them out, such insects when brought to Virginia, can stand a much heavier dose of poison without much apparent injury. This is one of our problems.

Senator COPELAND. Perhaps human beings will develop the same degree of resistance.

Mr. FRASER. He develops just the same.

Senator COPELAND. Excuse me for asking all this. Go ahead with your presentation.

Mr. FRASER. Now, Mr. Chairman, there are certain amendments which we would like made which will not detract in any way from the food purity or the protection of the consuming public.

The first one of those, which I already mentioned, is that of the standard of identity. I want to show you before I proceed what this involves. We are now under regulations of the Food and Drug Administration and the Bureau of Agricultural Economics on quality, and if we want to export, we may have to go under a third for inspection. If we are going under another standard, we have a question I think we might legitimately raise as to whether it is for any particular purpose. It will increase our expense. The apples on the north side of the tree and the apples on the south side of the tree are not alike. The apples on the top of the tree and the apples on the bottom are very different.

Senator COPELAND. I hope you are not going to propose that we just legislate for one side of the tree.

Mr. FRASER. Well, I am just wondering how you are going to get at it. If you are going to take a sample and you are going to destroy that apple, as you will in determining what the acid or sugar or other content is, and then when the apples reach their destination somebody draws a very different sample, and you find that they are not in accord with the first sample and you cannot give any sample of what you found in the first case, where are you going to land?

Let me give you our own case even with the present regulation.

Senator COPELAND. Are you referring now to a specific provision of the bill?

Mr. FRASER. I was taking the standard of identity. It is on page 10, lines 1 to 5.

When we sell a car the buyer frequently asks for Federal certificates. These cover grade, condition, spray residue, and may cost from $4 to $12 a car. These are based on samples. Reinspection may be performed by Federal agents at destination, again based on samples. Should reinspection fail to support the point of origin certificate the sale is void. The ownership of the car may revert to the shipper or grower. It may be 3,000 miles from production point and be a total loss and in addition to the loss of freight, packages, and the fruit, the grower may find himself subject to the penalties of this bill. To lose a car is a serious matter. I have pointed out the financial condition of the producer. He is anxious to avoid trouble.

Let me give you my own case in regard to standard of quality. I had a lot of apples in storage, and on December 4, I asked the Department to give me a certificate as to what mark I should put on them in order to be in compliance with the law. They say they are United States No. 1 and I shall mark them with regard to size, 2¼ inch. That certificate is prima facie evidence as to the size and quality of the goods. I moved them to New York. There, some inspector investigating finds four boxes out of the shipment which show 15 percent in one box of the apples below 2¼ inch. I am allowed a tolerance of 10 percent. I received a notice that the apples were misbranded and I was asked what I had to say before proceedings in prosecution should be instituted. I had the Federal certificate. It happens that in drawing a sample, we usually take the square root, in other words a carload of 170 barrels, we sample 13. If somebody samples another 13, you may get a very different answer.

If you are going to apply a standard of identity and make its infraction a criminal offense, for this is a criminal law, I see where you are going to be in an eternal turmoil, because no sampling will be adequate for all purposes.

If citrus want it, make it for citrus. You are here every year, but certainly do not go into such an interminable job as to take all fruits and vegetables and all natural food products and put us in a standard of identity and take a sample which passes the shipment at the point of shipment and may fail to pass at destination because of another sample.

Senator COPELAND. I think that you misunderstood or at least we apparently are not in agreement as to what is meant by a standard of identity. That would not refer to an apple. We have to determine, for example, what is ice-cream, and we say it cannot be sold as ice-cream unless it contains, we will say, 8 percent of butter fat, and so forth.

Mr. FRASER. That is a manufactured product.

Senator COPELAND. Yes; but when it comes to identity of an apple, I think that even I am able to tell that it is an apple.

Mr. FRASER. Well, then, leave us out.

Senator COPELAND. On the other hand when it comes to citrus fruit, I happen to go down to Florida once in a while and find the growers down there are very much wrought up, some of them, because they are permitted to send out unripe fruit, green oranges which they process and sell to us up in New York as nice yellow oranges, and when we get them we say that we do not want any more Florida oranges. I can see that there is a marked difference between standard of identity for an orange and a standard of identity for an apple. An apple is an apple. You do not paint it or glorify it in any way in its appearance, do you?

Mr. FRASER. We are not doing it now. We might find a way. [Laughter.]

Senator COPELAND. That is quite probable. But we do know that there are oranges sold, which are not oranges in their right sense. They are just painted humbugs.

Mr. FRASER. Let the citrus States handle their own standards. That is what they are doing now. In our judgment it is unthinkable that the Federal Government should be invested with power to establish the sugar, acid, and solid content of apples, raised under

all the varying conditions in a country as vast as this. As a matter of fact all raw agricultural commodities should be exempted.

Senator COPELAND. Have you any other point in the bill.

Mr. FRASER. That is the point I would like there, because we cannot see how you can make it work.

I will file this brief and in it cover that point.

I have given you the amendment the way we suggest that it go in, that no standard of quality or standard of identity shall be established for any fresh natural food, and provided further that in any regulations pertaining to fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food, and the use of necessary packing material.

Senator COPELAND. I realize that that is what you are requesting, but I have not made any promise that it will go in the bill, as far as I am concerned.

Mr. FRASER. All right.

Senator COPELAND. Don't they do that now? Don't they give consideration to the natural shrinkage in storage, and so forth?

Mr. FRASER. We have not any fill of container provision in effect, although we have fought this matter through Congress before. In this bill no appeal from a regulation is possible.

Senator COPELAND. I think it might be well for you to say a few words on that particular provision.

Mr. FRASER. I think you might very advisedly draw attention to the fact. For instance, bananas shrink 1 percent a day in transit in weight, and the Italian peddler, of course, comes to know that. He begins to realize what is going on when he buys them by weight, and he aptly says, "he maka on the peanut and losa on the damn bananan", and he knows how. He comes to the point pretty quickly, though. So, on the standard of fill of container, the natural shrinkage should be allowed for, because it takes place in transit, and we cannot afford to have anything going into destination rattling if we can avoid it.

Senator COPELAND. Tell me, Mr. Fraser, are apples sold by weight?

Mr. FRASER. When sold in bulk they may be. When packaged no, they are then sold by the container, both at wholesale and retail, the Federal law provides for a bushel. This is administered under the United States Bureau of Standards and Department of Agriculture.

Senator COPELAND. What you are proposing in your amendment is that you want it to be called a bushel at the time the bushel basket is filled, and that if there should be natural shrinkage of the units of the bushel that that should be given consideration.

Mr. FRASER. Absolutely; because to repack would reduce its value so much in case of some of these commodities that the man would much rather have them just a trifle short of tight than to have them repacked.

Senator COPELAND. Would there be a probability that that would mean that the consumer would be cheated, that he would get less than he was expecting to get when he buys a bushel of apples?

Mr. FRASER. They practically never buy them that way. They buy them by the pound, unit, quart, or peck, after bulk is broken.

Senator COPELAND. I notice in my orchard that when they pack the apples it rounds up over the top of the bushel basket.

Mr. FRASER. We do it on purpose.

Senator COPELAND. Is that done because there has to be shrinkage?

Mr. FRASER. Certainly.

Senator COPELAND. So that perhaps when it reaches merchant that it will be down to the level?

Mr. FRASER. That is right. In a Ben Davis, in 173 days in storage we may have as much as 14 percent shrinkage, due to the face that the plant is alive and it is drawing on the sugar and the water for its sustenance, and it must live. It must be furnished with some source of heat and fuel, and you cannot have it otherwise in order for it to live, so the longer we hold it the lighter it gets or the smaller it gets, until at some time it breaks right down, due to the break-down of the calcium pectinate which is holding the cells together.

Senator COPELAND. That happens with fish, too, doesn't it? There is a reduction in the weight and size of a fish as time goes on?

Mr. FRASER. I don't know anything about fish.

Senator COPELAND. I saw a statement on a sea horse, where a man said he found a sea horse 14 inches long, but when they came to measure it up a few days later it was only 12 inches long.

Mr. FRASER. I am going to keep off fish stories. [Laughter.]

Senator COPELAND. So you propose there should be an added proviso that in any regulations pertaining to fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of the fresh, natural food.

Mr. FRASER. Yes. You pack this fruit in the fall and put it in storage where it may remain from 1 to 8 months. Some shrinkage is inevitable and you can't repack it without injury to the fruit.

Senator COPELAND. I want to be assured of this: Would that be apt to result in fraud upon the consumer?

Mr. FRASER. Absolutely no.

Senator COPELAND. Have you said now all that you care to on that subject?

Mr. FRASER. I think so. I cannot see any fraud that would come in.

Amendment no. 2 is section 702——

Senator COPELAND (interposing). Excuse me just a minute, Mr. Fraser. If you must sell a bushel, why do you need this amendment?

Mr. FRASER. Because in some cases we have to put a liner in the package in order to protect it or cushion it. And we have to put cushions top and bottom in order to reduce the pressure damage when we put the top on.

Senator COPELAND. Do you mean the damage to the fruit?

Mr. FRASER. Yes. And we had a great fight in one case to make Congress realize that that was an essential. They wanted the whole package filled with apples, regardless of the amount of cushioning necessary.

For instance, that egg container of which I talked—and you have seen them—we have a space filled up by the cardboard between each

layer, and for certain trade in New York that is the only way to get the apples through. They want a perfect apple and will pay for it.

Senator COPELAND. Of course, it is quite different, eggs and apples, because when you buy eggs, you buy so many dozen eggs.

Mr. FRASER. I sell those apples by the count. Those that are sold that way are by count. We can sell by count, weight, or volume. That is provided in law. There is no deception. I say eighty 2¾-inch apples in the box. Every apple must be two and three-quarters, except for a tolerance which the law provides.

Senator COPELAND. When you put this cushion in, do you make a false bottom to lift it up from the bottom?

Mr. FRASER. I put cushions on the bottom in some cases when they are going express; otherwise they would not get there. In other cases, one has to use a corrugated cap or a cushion on the top to take up the shrinkage in storage and so that the fruit will not rattle around in transit. The packages have to be tight or so handled that the fruit will not bruise in transit by the fruits pounding against each other.

Senator COPELAND. Have you still got left a bushel of apples then?

Mr. FRASER. Yes. In my case I have the number which I mark on the container when they are sold by amount, for example—80 three-inch apples.

Senator COPELAND. Then it will be safer for the consumer to buy by number rather than by the dry measure.

Mr. FRASER. Not at all. He is safe either way. This is a continent 3,000 miles wide, and you will have to allow for all of the vagaries of commercial requirements.

Senator COPELAND. As well as of nature.

Mr. FRASER. Yes; both. We have to satisfy the consumer and have no argument with him. We take his money and give him what he thinks he wants.

Senator COPELAND. All right; go ahead.

Mr. FRASER. Section 702, page 25, lines 17 to 24, and page 26, lines 1 to 25.

I have drawn attention to the people whom we are legislating for, and I believe that it is wise to keep it in mind. Congress considers the consumer and it is also considering the people who are doing this business. It must be constantly kept in mind that this bill, largely, if not entirely, reverses the long-established and proper procedure in criminal cases. This is a criminal law. The violation of this proposed act is a criminal offense punishable by fine or imprisonment, or both, section 708, 709, and 710. It should not be confused with civil suits.

Under the present law and the established principle of common law and Anglo-Saxon procedure in criminal cases, the Government or the people must first prove their case against the defendant from the ground up. The burden of proof is on the prosecuting agency. The defendant then has the opportunity to prove himself innocent on both the fact and the law.

Secondly, under this proposed act, the burden of proof is either largely or entirely shifted in the first instance to the back of the defendant, and, in addition, in a great mass of cases he will not be able to question the regulations of the Secretary on the facts.

You have gone a long way in this in protecting the consumer. You are going to make me prove that I am not in conflict with this law. Instead of proving that I am in conflict, you are going to make me prove that I am not in conflict with it, and in addition, in a great mass of cases, it will not be possible to question the regulations of the Secretary on the facts.

Let us see briefly what will happen. The Secretary, in conjunction with the advisory committee, promulgates a regulation based on such facts as may have been assembled, and, presumably, after weighing and balancing such statements, views, and opinions as may have been presented. A hearing is held prior to such regulation. There may be many or only a few who participate. Many will not even know about the hearing. It may or may not be exhaustive. New and vital facts may be available even before or after promulgation, or experts may have changed their opinions after the promulgation of the regulation.

There is no procedure outlined in this measure whereby the public, the citizen, or even the advisory committees can initiate amendments to the regulations in the light of new facts or for any other reason. The initiative is lodged entirely in the hands of the Secretary on both the original regulation and the possibility of amendments. (See p. 28, par. C.)

The regulation is promulgated, and the Secretary then reports to the district attorney that Tom Jones has violated the regulation. The district attorney starts criminal prosecution, and all that Tom Jones can do is to prove that he did not violate the regulation. He cannot go into the facts underlying the regulation, except under conditions which in the great majority of cases prevent him from going into such facts.

The crux of the whole matter is the regulation and the facts on which it is based. The violation of the regulation is secondary. Limiting Tom Jones to merely proving that he did not violate the regulation is to deprive him of full legal rights, and in a large sense places his guilt in the hands of administrative officers and bureaus.

Tom Jones, the defendant, cannot go into the facts surrounding the regulation, or the facts on which the regulation is supposed to be based, unless he can prove that the regulation is unreasonable, arbitrary, or capricious, or not in accordance with the law, in the light of the facts.

This burden of proof is on Tom Jones, the defendant, and not on the Government to prove that the regulation is not unreasonable, not arbitrary, not capricious, and is in accordance with the law.

Just how far will Tom Jones get in contesting a regulation by injunction or as a defense in a criminal suit on the above ground which he is required to show under this proposed act?

It is true there might be in some instances such a gross disregard of facts and procedure in promulgating a regulation, that Tom Jones may be able to show that the regulation was unreasonable, arbitrary, or capricious, or not in accordance with law, but there is a great vast field where he would be unable to show any of these grounds in the sense required by the courts, and where the court

would not overturn the regulation or grant relief from it, even though such regulation were contrary to the weight of evidence and contrary to what the court itself would decide to be a proper regulation. Moreover, there is nothing in this proposed statute to require the acceptance of newly discovered evidence bearing on the regulation.

It would seem to be well settled by the courts that to obtain relief from a regulation or order of an administrative branch in civil proceedings, where such administrative body has been authorized to issue a regulation or order, on the ground that it is unreasonable, arbitrary, or capricious, the defendant, or the party who calls it in question, has to show such a gross disregard of facts in promulgating the regulation as to in itself constitute an error of law. If there is any competent evidence to sustain the regulation, the court will not disturb it.

The addition of the words "In the light of the fact", in line 2, page 26, means practically nothing from a legal standpoint, if there is any substantial evidence to support the regulation.

In the case of *Interstate Commerce Commission* v. *The Union Pacific Railroad Co.* (222 U. S. 541), Mr. Justice Lamar, in handing down the decision of the United States Supreme Court stated certain things which may be copied in, but I won't read them.

Therefore, if the Secretary has any substantial evidence to support his regulation, it will not be disturbed, even though the courts might or would have come to a different conclusion of the fact.

It is one thing to have such a situation prevail in civil suits or proceedings for damages, but an entirely different matter where criminal liability or the destruction of one's property, or both, are involved. We do not approve the principle even in civil suits or proceedings.

Senator COPELAND. Mr. Fraser, would you mind putting that in the record, the rest of your argument?

Mr. FRASER. It is only very short. We have drawn attention to it in S. 1944, and if you will print this in its entirety, that will be ended.

Senator COPELAND. We are extending the record to put it in in full. Let me discuss it for a moment; let me say to our friends who are here that the reason I am taking so much time on this subject is because we have two things to think of. We must think about the welfare of these great industries affected, but beyond that and more important is the public health. Last night, Mr. Fraser, you and I discussed this item.

Mr. FRASER. Yes.

Senator COPELAND. And at that time you proposed inserting at the top of page 26—and I think it appears at another place too—line 2, page 26, inserting, "existing", to read, "In the light of the existing fact." I have talked to nobody about this since I have talked with you, Mr. Fraser, but I have thought about it. Yesterday I felt rather sympathetic to your contention, and let me say now why I think I was wrong, and this is out of my own thought. These regulations, in spite of what you have said a few minutes ago, are made, on page 28, line 9, with the approval of a majority of the members of the Food Committee.

Mr. FRASER. Some of them; only some.

Senator COPELAND. The approval of a majority of its members.

It reads, beginning on line 10, page 28:

> the committee shall recommend to the Secretary a proposed regulation, and the Secretary shall give notice of the proposal and of the time and place of the public hearing to be held thereon not less than 30 days after the date of such notice.

It may be that this language is defective; we might need to give a longer notice, but the point is that the regulation is not made until the committee had considered it and in that food committee the producer would be represented, and so it would be argued out there, and then a majority of the members would decide that the regulation was a wise one. So stating to the Secretary, the Secretary would give notice of the public hearing, presumably 30 days later. Perhaps we ought to change that, but anyway the public has been put on notice that such a regulation or resolution is in the offing. The regulation is then made, and it is made in the light of the facts presented in the hearing, and the regulation is regarded to be capricious, or as the language states, "unreasonable, arbitrary, or capricious." What regulation? It was a regulation that was made in view of the testimony adduced and in the light of the facts presented at the time of making the regulation.

I do not think it would be fair to the Government, to the Department, to go into court and present new facts. If you have new facts which would indicate that this is an unreasonable regulation, the orderly procedure would be then for the committee and for the Secretary, and after due hearing, to make a new regulation or a modification of the old one.

Mr. FRASER. And I would be in jail.

Senator COPELAND. If you will bear with me for a moment. You go into court to show that the regulation made in the light of the testimony and in view of all the circumstances, that the regulation which you are seeking to set aside was unreasonable or arbitrary. I do not believe this morning that it would be fair to bring into a case new testimony that it was an unreasonable regulation. I can see that these regulations should be in flux. There should be perhaps greater latitude or more frequent meetings to determine upon the regulations, but I do not believe, after thinking the matter over, that you ought to go into court and say, "Well, the regulation might have been all right, but it was made at that time and it was all right when it was made, but we have found out a lot of things about it since then." That is the way it strikes me.

Mr. FRASER. Then, you see, you have no review, and you and I have arrived at the same point, that there is no review for the man who is alleged to be in violation, because the court will certainly just look at the record and it will find that before the regulation was promulgated, the Secretary had certain evidence in favor of it, and even though a reexamination would lead the court to reverse that regulation, they will not so find.

Senator COPELAND. You make your argument, but I am telling you how it strikes me. I do not know what the other members of the committee will think about it.

Mr. FRASER. Furthermore, you have mentioned certain regulations only. You have left the Secretary free to issue any regulations he desires. To promulgate regulations under section 701——

Senator COPELAND (interposing). Yes; but that committee promulgates regulations. That is not to make regulations.

Mr. FRASER. What is the difference?

Senator COPELAND. I think there is a very great difference. The committee, acting under the machinery of the bill, the regulation is determined upon, and then he gives publicity to it. I do not think that language of section 701 that you have just referred to at the top of page 25, because we deliberately struck out "make" and said "promulgate" and there is a very great distinction.

Mr. FRASER. But in the case of 701 (b), what is the position of the Secretary of the Treasury then with regard to exports and imports, if he cannot make them?

Senator COPELAND. I do not think you are particularly excited about that, are you?

Mr. FRASER. It is important; it has a bearing on the position of (a).

Senator COPELAND. No; because——

Mr. FRASER (interposing). They are identical.

Senator COPELAND. No; they are not identical. They deal with different things. A is our purely domestic procedure, while B has to do with section 714, which is the export clause, is it not?

Mr. FRASER. Yes.

Senator COPELAND. I do not think that you can find in this bill—personally I have tried to keep it out of the bill because that was my objection to the Tugwell bill—that arbitrary authority was given to the Secretary of Agriculture, and you did not have any relief there. He could just think about it and make his regulation, but now this provision that you are discussing this morning is a regulation which has been made in an orderly fashion by a hearing before the committee, and a majority of them determining that it is necessary, and then after public hearing the regulation is formulated, and then under 701 it is promulgated. I really think, Mr. Fraser, that it would be asking too much of us to insert there "existing fact" of a regulation which was made at one time, even though there might be a development in the methods of control—for instance, of spray residue; it would not be reasonable to have the court then take testimony on the present state of affairs when you are dealing with a problem out of which came the regulation itself. If there are places in this bill where we have left the public—and we will say, in your case, the producer of apples—if we have not given you time enough or publicity enough to know what is going on, that is different; but so far as the regulation is concerned and the court, I would say certainly that the question involved here and which would be presented to the court would be, Was the regulation, when it was made, arbitrary, unreasonable, and capricious?

Mr. FRASER. Of course, we would reach the position we have outlined—that we would find a closed door, because it is distinctly now understood that the regulation, the finding back of it, cannot be reviewed, we cannot review the facts.

Senator COPELAND. You ought to have an open door, so far as the field of the Department is concerned, to make a new regulation or to modify a regulation; but when a regulation is once made it never would have any effect, because at any time there might have been a change in the weather or something, and you could go and ask that, in view of new weather conditions, that we have a change in the regulation. I think your attack on the bill is at a wrong place.

Mr. FRASER. Just take another point. The finding and conclusions of the Department of Agriculture officials respecting adulteration and misbranding today has been held tentative and not binding in the case of the National Remedy Co. against Hyde, in the District of Columbia court at the present time, so that you could get a review. Now, you are making this so that you cannot get a review. You are asking me to point out where you made this bill stronger, and I am showing you what I very much believe might be modified, because I can see, for instance, we might develop an arsenical compound organic, for instance, which would be toxic to insects and not detrimental to man any more than the present is in cod-liver oil, and then we would be prohibited from showing more on our fruit than we are at the present time, and we could not get a review.

Senator COPELAND. I am going to make just one more comment, and then I will stop, because we are taking up too much of the time of the committee, but I did it deliberately because I am not flattering Mr. Fraser; I know he is an intelligent witness, and I wanted to have somebody to bring out these facts, but I want to say this one thing and then I will be through. I think on page 28 there might well be inserted that the proposal and the time and place of public hearing to be held thereon, except on a matter where the public health was involved, that there might be a longer period than 30 days in order that there may be greater consideration given.

Mr. FRASER. I am not so concerned over that point, Senator, as over the real right of my day in court, and I do not feel it would hurt the bill at all, because in the Perishable Agricultural Commodities Act, which I direct your attention to, which is under the Department, where the Secretary makes the regulations, he makes a finding and there is nothing to stop a person, feeling himself aggrieved, going into court, and the Secretary files all of his evidence, and that man must overcome that mass of evidence in order to get a reversal, but the court can consider both sides, and in this it is closed. A regulation will not be reviewed as it is written in S. 5. You cannot enter court for review. In the case of the Perishable Agricultural Commodities Act, which is under the Secretary of Agriculture, the matter can be reviewed and a trial de novo had, but the Secretary of Agriculture's finding and his regulations are presented as a matter of prima facie evidence, and it requires a great deal of evidence to overcome that regulation. The court will give all they can to any such regulation, but certainly I would not shut the door.

I had only one suggestion on section 701, and that was that the amendment read in this fashion:

> SEC. 701 (a). The authority to promulgate such regulations as are specifically provided for by the terms of this act, except as otherwise provided in this section, is hereby vested in the Secretary.

The adoption of this amendment will exactly express the actual intention of the bill and prevent any uncertainty as to the meaning of the paragraph.

The only other things which we have are our proposed amendment no. 3, on page 42: "and if it appears to the court that such proceeding is necessary to effect the purpose of the act." On page 42, line 9, insert a comma after the word "found" and followed by the phrase I have just read.

Also, I would like to endorse an amendment which I understand has been proposed for section 711 C, page 43, either the end of page 43 or the top of page 44, which I believe I submitted last night for consideration.

Senator COPELAND. Is there a copy for the record:

In cases involving adulteration, the Department shall file with the person accused, its analysis on which the alleged adulteration is based and the method in detail used in making such analysis. A representative sample of the commodity analyzed and a copy of the regulation with which such analysis is alleged to be in conflict.

Mr. FRASER. Mr. Chairman, I wish to thank you very much for all of the consideration you have given, and assure you of our continuing support in the administration of the act and the support of the Department in every way, and I would like to take this occasion to give expression to our appreciation, the appreciation of the industry itself for the able manner in which you have handled it.

BRIEF OF INTERNATIONAL APPLE ASSOCIATION, R. G. PHILLIPS, SECRETARY, ROCHESTER, N. Y.

PREFACE

We wish to again emphatically state and to make plain beyond a shadow of doubt, as we have in previous statements during the progress of this measure from its inception as S. 1944, that no industry has given greater or more constructive support to pure-food laws and to the Federal Food and Drugs Administration than the apple and pear industries. That support still continues but it does not mean that any industry or any citizen is under obligation to accept without constructive criticism and suggestion any and all proposals that may be advanced.

All we have been or now are interested in is to secure a proper law.

The bill as it stands is superior to its predecessors.

There are, however, certain amendments which should be made and which will detract in no way from food purity or the protection of the consuming public.

Those amendments are discussed in the following pages.

AMENDMENT NO. 1, DEFINITIONS AND STANDARDS FOR FOOD, SECTION 303, PAGE 9, LINES 22 TO 24, AND PAGE 10, LINES 1 TO 5

1. "Standards of identity", page 10, line 2: Apples and pears should be exempted.

Under the provision as it now stands, the Secretary can promulgate "standards of identity" for apples and pears.

Under that grant of power he could fix the sugar content, and the acid content and the solid content of these fruits, and it would be a violation of the act, criminal in character (sec. 302 (g), p. 7, and sec. 708 (a) to (g), pp. 34–40; secs. 709, 710) to market in interstate commerce anything that was below the standard promulgated.

The sugar, acid, and solid content of these fruits vary materially with the variety (of which there are hundreds), the character of soil, the region, the location, the age and care of trees, and the marked difference in growing seasons, as between a hot or cool season, dry or wet, and all the varying and changing climatic conditions.

It must be borne in mind that apples are produced from New England to the mountain sections around Los Angeles and from Georgia to the Canadian line in the State of Washington. There is a great variation in the natural conditions in a country as vast as the United States.

These raw fruits are raised in the last analysis primarily by the Almighty or natural conditions. The producer cannot control the weather; he cannot change the character of his soil; he cannot remove his orchard to some other place.

It would be simple enough to fix the "standard of identity" so high as to eliminate from commerce varieties and sections in whole or in part.

While "standards of identity" might be fixed for fabricated or processed food, the Secretary should not have the power to fix them for apples, pears, or any other fresh or raw agricultural commodity, raised under the widely varying natural conditions in this country.

It is no answer to say that the Secretary will not fix such standards for apples and pears. It is a wrong principle in legislation to grant power on the assumption that it will not be used. No one knows what may happen.

If the Secretary does not intend to fix such standards and does not wish to fix them, then let the exemption be plainly written into the act.

If he does intend to fix such standards, then, by all means, it should be made clear that it must not be done.

If any State wishes to establish the sugar, acid, and solid content of anything that it produces, under the conditions peculiar to that State, then that is a matter for the State to decide. The Federal Government, however, should not even want, much less ask, power to impose a standard for the entire country under the widely varying natural conditions which maintain.

2. "Standards of fill of container", page 10, line 3: Natural shrinkage should be provided for. Such shrinkage is inevitable in storage and often in transit, as applied to apples and pears or any other fresh fruit and vegetable.

3. Amendment requested: Amend lines 4 and 5, section 303, page 10, after the word "container" in line 4 to read as follows: "*Provided*, That no standard of quality or standard of identity shall be established for any fresh natural food: *And provided further*, That in any regulations pertaining to fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and the use of necessary packing material."

AMENDMENT NO. 2. COURT REVIEW OF REGULATIONS AND ADMINISTRATIVE ACTIONS

1. Section 702, page 25, lines 17 to 24, and page 26, lines 1 to 25:

First. It must be constantly kept in mind that this bill largely, if not entirely, reverses the long-established and proper procedure in criminal cases. The violation of this proposed act is a criminal offense punishable by fine or imprisonment or both (secs. 708, 709, 710). It should not be confused with civil suits. Under the present law and the long-established principle of Anglo-Saxon procedure in criminal cases, the Government or the people must first prove their case against the defendant from the ground up. The burden of proof is on the prosecuting agency. The defendant then has the opportunity to prove himself innocent on both the facts and the law.

Second. Under this proposed act, the burden of proof is either largely or entirely shifted in the first instance to the back of the defendant and, in addition, in a great mass of cases he will not be able to question the regulations of the Secretary on the facts.

Let us see briefly what will happen. The Secretary, in conjunction with the advisory committee, promulgates a regulation based on such facts as may have been assembled and, presumably, after weighing and balancing such statements, views, and opinions as may have been presented. A hearing is held prior to such regulation. There may be many or only a few who participate. Many will not even know about the hearing. It may or may not be exhaustive. New and vital facts may be available either before or after promulgation, or experts may have changed their opinions after the promulgation of the regulations.

There is no procedure outlined in this measure whereby the public, the citizen, or even the advisory committees can initiate amendments to the regulations in the light of new facts or for any other reason. The initiative is lodged entirely in the hands of the Secretary on both the original regulation and the possibility of amendments. (See p. 28, par. (c).)

The regulation is promulgated. The Secretary then reports to the district attorney that John Jones has violated the regulation. The district attorney starts criminal prosecution, and all that John Jones can do is to prove that he did not violate the regulation. He cannot go into the facts underlying the regulation, except under conditions which in the great majority of cases would prevent him from going into such facts. The crux of the whole matter is the regulation and the facts on which it is based. The violation of the regulation is secondary. Limiting John Jones to merely proving that he did not violate the regulation is to deprive him of his full legal rights and in a large sense places his guilt in the hands of administrative officers and bureaus.

John Jones, the defendant, cannot go into the facts surrounding the regulation or the facts on which the regulation is supposed to be based, unless he can prove that the regulation is unreasonable, arbitrary, or capricious, or not in accordance with law.

This burden of proof is on John Jones, the defendant, and not on the Government to prove that the regulation is not unreasonable, not arbitrary, or not capricious and is in accordance with law.

Now, just how far will John Jones get in contesting a regulation by injunction or as a defense in a criminal suit on the above grounds which he is required to show under this proposed act?

It is true there might be in some instances such a gross disregard of facts and procedure in promulgating a regulation that John Jones might be able to show that the regulation was unreasonable, arbitrary, or capricious, or not in accordance with law; but there is a great vast field where he would be unable to show any of these grounds in the sense required by the courts and where the court would not overturn the regulation or grant relief from it, even though such regulation were contrary to the weight of evidence and contrary to what the court itself would decide to be a proper regulation. And, moreover, there is nothing in this proposed statute to require the acceptance of newly discovered evidence bearing on the regulation.

It would seem to be well settled by the courts that to obtain relief from a regulation or order of an administrative branch in civil proceedings, where such administrative body has been authorized to issue a regulation or order on the ground that it is unreasonable, arbitrary, or capricious, the defendant or the party who calls it in question has to show such a gross disregard of facts in promulgating the regulation as to in itself constitute an error of law. If there is any competent evidence to sustain the regulation, the court will not disturb it. The addition of the words "in the light of the facts" in line 2, page 26, mean practically nothing from a legal standpoint, if there is any substantial evidence to support the regulation.

In *Interstate Commerce Commission* v. *Union Pacific Railroad Co. et al.* (222 U. S. 541), Mr. Justice Lamar in handing down the decision of the United States Supreme Court, said, among other things:

"These appeals raise the single question as to whether, in making the 45-cent rate, the Commission acted within or beyond its power * * *.

"In cases thus far decided it has been settled that the orders of the Commission are final unless (1) beyond the power which it could constitutionally exercise; or, (2) beyond its statutory power; or (3) based upon a mistake of law, but questions of fact may be involved in the determination of questions of law so that an order, regular on its face, may be set aside of if it appears that (4) the rate is so low as to be confiscatory * * *; or (5) if the Commission acted so arbitrarily and unjustly as to fix rates contrary to evidence, or without evidence to support it; or (6) if the authority therein involved has been exercised in such an unreasonable manner as to cause it to be within the elementary rule that the substance and not the shadow determines the validity of the exercise of the power.

"In determining these mixed questions of law and fact the Court confines itself to the ultimate question as to whether the Commission acted within its power. It will not consider the expediency or wisdom of the order, or whether, on like testimony, it would have made a similar ruling * * *. Its conclusion, of course, is subject to review but, when supported by evidence, is accepted as final; not that its decision, involving, as it does, so many and such vast public interests, can be supported by a mere scintilla of proof, but the courts will not examine the facts further than to determine whether there was substantial evidence to sustain the order."

Therefore, if the Secretary has any substantial evidence to support his regulation, it will not be disturbed even though the courts might or would have come to a different conclusion on the facts.

It is one thing to have such a situation prevail in civil suits or proceedings for damages, but an entirely different matter where criminal liability or the destruction of one's property, or both, are involved. We do not approve the principle even in civil suits or proceedings.

In this proposed law you have the Secretary acting as a legislative and judicial body in promulgating a regulation, the violation of which is a criminal offense. The Secretary then decides as an executive officer that you have violated his regulation and notifies the district attorney to prosecute you. In endeavoring to defend yourself, you are denied the right to question his legislative and judicial acts on the facts, except under conditions which you will be unable to meet in the vast majority of cases, because in most instances at least there will be some evidence to support the Secretary's legislative and judicial acts (*Interstate Commerce Commission* v. *Union Pacific Railroad, supra*).

Imperfect as the courts may be, experience has not yet shown a better method of protecting the public or safeguarding the fundamental rights of the citizen. That is what the courts are for. Certainly the regulations of administrative officers, bureaus, and advisory committees should not be permitted to supersede the courts in criminal cases, in whole or in part, or to precent a citizen from having his full and complete day in court on all of the facts and all of the law. And we know of no legitimate or fundamental reason why the United States Government, above all others, should not itself insist upon guaranteeing such rights beyond a shadow of doubt.

We have fought for this principle since the inception of S. 1944. It is the most vital principle in this proposed law.

2. Proposed amendment: Amend section 702, page 25, lines 19 to 24, and page 26, lines 1 to 25, to read as follows:

"SEC. 702. The district courts of the United States are hereby vested with jurisdiction, on petition of any interested person, (1) to restrain by injunction, temporary or permanent, the enforcement by any officer, representative, or employee of the Department of any regulation promulgated as provided in sections 701 and 703 if it is shown that the regulation is unreasonable, arbitrary, capricious, or not in accordance with the facts, or not in accordance with law, and that the petitioner may suffer substantial damage by reason of its enforcement; and (2) to grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the Department in the administration of this act, if it has been shown that such act or omission is unreasonable, arbitrary, or capricious, or not in accordance with the facts, or not in accordance with law, and that the petitioner may suffer substantial damage thereby; and any such suit under paragraphs (1) and (2) hereof shall be a trial de novo on both the facts and the law: *Provided*, That nothing in this section shall be deemed to abridge the right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this act, or who shall intervene as claimant in any proceeding of libel for condemnation to plead and/or show that the regulation, the violation of which is alleged as the ground for such prosecution, suit, or libel, is illegal and/or contrary to fact."

Comment.—Under the above it will be noted that the burden of proof is squarely on the shoulders of the person who calls the regulation in question. The Secretary, in the first instance, does not even have to prove that his regulation is not unreasonable, not arbitrary, or not capricious, or that it is in accordance with the facts or the law. We do not approve of the principle in criminal cases of shifting the burden of proof and, in substance, presuming a defendant to be guilty. Nevertheless, the amendment which we emphatically urge does give an interested person his full day in court on all of the facts and all of the law, even though the burden is on his shoulders. Certainly nothing less than this should prevail.

Under the Perishable Agricultural Commodities Act (48 Stat. 584) the Secretary of Agriculture (sec. 7 (a)) is empowered to determine the damages sustained by a person by virtue of violation of certain provisions of the act and to issue reparation orders, and the findings and orders of the Secretary are made prima facie evidence of the facts therein stated; but on any suit

brought in the district court to enforce the order the defendant can go into all of the facts underlying the findings and order and the trial proceeds like any civil suit for damages (par. (b)).

Furthermore, the findings and order of the Secretary can be appealed direct to the district court and, quoting from the act (sec. 7 (c)):

"Such suit shall be a trial de novo and shall proceed in all respects like other civil suits for damages, except that the findings of fact and order or orders of the Secretary shall be prima facie evidence of the facts therein stated."

Under the above act we find that in these civil suits the defendant or party aggrieved does have his full day in court on the facts entering into the findings and order of the Secretary, or any other facts which the party is able to present. He does not have to prove that the Secretary's order or findings are unreasonable, arbitrary, or capricious as a condition precedent to review or relief.

When we come to the pending proposed Food and Drugs Act—a criminal statute—we find that the defendant or person aggrieved is not only denied the rights granted to him in civil suits under the Perishable Agricultural Commodities Act, but that his right to a full day in the duly constituted court on the facts is so tenuous and nebular as to be negligible.

To say the least, such a situation or proposal is astounding.

The position has been advanced that the change in the legal principles of the present law is desired because the Government does not wish to go to the time and expense of following the usual and sound procedure in criminal cases and prove its case in each instance, and further that the principles incorporated in the Perishable Agricultural Commodities Act and in the amendment which we urge would result in a vast number of suits. The answers to the above are two:

First. There have been no large number of suits under the Perishable Agricultural Commodities Act. The practice there laid down has resulted in due care and a sound regard for the rights of the citizen.

Second. The least any sovereign power can or should do is to guarantee its citizens their full day in court, even though such practice involves some cost and time, and particularly since the citizens pay the cost in their taxes. It is unthinkable to even attempt to deprive one of fundamental rights on the ground of time and cost.

AMENDMENT NO. 3

Amend section 711 (a), page 42, line 9, by placing a comma after the word "found" and inserting the following: "if it appears to the court that such proceeding is necessary to effect the purpose of the act."

AMENDMENT NO. 4

Amend section 711 (c), page 43, line 25, by inserting after the word "seized" the following:

"In cases involving adulteration the Department shall file with the person accused its analysis on which the alleged adulteration is based, the method in detail used in making such analysis, a representative sample of the commodity analyzed, and a copy of the regulation with which such analysis is alleged to be in conflict."

It is only fair and proper that the person accused should know exactly what the Secretary feels he has found in or on the commodity and the amount or quantity, and, furthermore, the method used in such analysis. He is also justly entitled to a representative sample and a copy of the regulation which he is alleged to have violated. None of these things have heretofore been granted as a matter of right and in many instances the defendant has been materially in the dark.

Senator GIBSON. Mr. E. J. Lever.

STATEMENT OF E. J. LEVER, PRESIDENT OF COOPERATIVE DISTRIBUTORS, INC., NEW YORK, N. Y.

Mr. LEVER. My name is E. J. Lever, and I represent Cooperative Distributors, Inc., of New York.

Senator GIBSON. Have you a prepared brief?

Mr. LEVER. I have a brief which requires some comment. It is very short, Mr. Chairman.

Senator GIBSON. We have to conserve our time.

Mr. LEVER. Mr. Chairman, to begin with, representing the consumers' cooperative movement, we wish to endorse the statement made by Miss Alice Edwards, representing the 11 women's organizations, who spoke for the consumers' point of view in her testimony yesterday.

In addition, the Democratic administration had as a part of its program when it was elected, the passing of a strong food and drugs bill We believe that it owes it to the consumers of this country, and we hope that a strong food and drug act will be passed at this session of Congress.

We are one of the organizations that filed a brief last year in support of the Tugwell bill. We recognized certain limitations of the Tugwell bill, but it was the best to be had at that time. We now substantiate our desire and speak for a much larger number of consumers, both those in the city and on the farm.

Observing the testimony presented before the Senate committee on the food and drugs bill, one is clearly impressed that there are two distinct forces engaged in this struggle for and against strong food and drug legislation.

The first, and by far the most numerically represented here, are the manufacturers of food, drugs, and cosmetics who have something to sell to the ultimate consumer at a profit. The second is composed of representatives of the ultimate consumer who are determined to control the intense enthusiasm of food and drugs manufacturers and the advertising fraternity to guzzle poisonous foods, drugs, and medicaments down the throats of the American people.

How much resentment has been raised against poisoned and adulterated foods and the extremely unethical manner by which they are sold may be gauged by the fact that briefs in support of this bill have been presented here by such organizations as the Y. W. C. A., the American Home Economics Association, the American Association of University Women, the League of Women Voters, the General Federation of Women Clubs, and several professional, medical, and pharmaceutical organizations. In addition to their protests and demands for a strong food and drugs law, there has grown up a resentment among the farmers, wage earners, and professional people of this country who in the past few years have rapidly organized for self-protection into a consumers' cooperative movement which at the present time comprises some 2½ million people. At the last Cooperative Convention in Chicago in October 1934, a resolution demanding that Congress pass a strong food and drugs bill was passed unanimously by some 300 delegates representing hundreds of thousands of organized consumers. So conscious have organized consumers become of the necessity for protection that demands are being made for a department of the consumer in the Federal Government, originally suggested by Consumers' Research, Inc., which will no doubt grow out of this agitation in much the same manner as the Department of Labor grew out of the labor movement.

One is amused to find the claims made by food and drugs manufacturers, publishers, and the advertising interests that they speak

for the consumer. One of them actually went so far as to state that he spoke for 50,000,000 consumers because these consumers bought his magazines. Gentlemen of the Senate committee, just who authorized such people, who are in business solely for profit, to speak for the consumer? When I buy a magazine, perhaps to check up on how many more lies the advertising fraternity has used this week than last to sell somebody's horse liniment for human consumption, I certainly, by no stretch of the imagination, authorize the publisher of that magazine or anyone connected with it to speak for me as a consumer. Representation in the ethical and legal sense, as we understand it, may be best illustrated by the authority of your committee. You are duly elected by your constituencies in some authorized and regular manner as members of the United States Senate.

Unlike the food and drug manufacturers and their advertising allies, the representatives of consumers at this hearing are here because they have been actually authorized by their memberships to speak in their behalf.

As representatives of the organized consumers cooperative movement, we deny to merchants, publishers, manufacturers, and their advertising allies the right to speak for us as ultimate consumers. They represent only their own particular profit interests and their claims to represent the ultimate consumer are wholly without foundation.

The same holds true about the claims of some to speak for their employees. That is the job of the labor movement and as trade-unionists we deny employers the right to speak for us as workers. We know what we want and we insist on speaking for ourselves through our duly authorized representatives, not through employers.

All the material so far presented here fails to put the finger on the sorest spot of the whole problem. Advertising is the means through which all this adulterated junk is unloaded on us as consumers. Emphasis has been placed here by some, including ourselves, on the necessity for disclosing the formula on the label. But the advertising fraternity knows that it is not the label that sells the product, it is advertising of the product far in advance of the consumer seeing the label itself. By that means he is made to want the particular product so much that, irrespective of a warning on the label, he is bound to buy it.

No greater example of uncurbed advertising need be had than in the repeal of the eighteenth amendment, in which Congress failed to forbid the advertising of whisky and other alcoholic products. As a result, tremendous space is devoted to selling whisky by every conceivable means. Even a cursory examination of uncurbed advertising in this field supplies sufficient evidence that the immature minds of the young are being shaped to such a degree in favor of alcohol that they can hardly resist the temptation.

Imagine yourselves when you were 7 and 10 years old seeing the kind of advertising that is being done for whisky today, you would almost imagine that whisky was more necessary than bread for your existence and that you could hardly have a good time without it, which is not true. Ice cream, perhaps, would do a better job.

We are not prohibitionists and do not need to be to observe how far uncurbed advertising will go to sell many more poisonous products as long as there is a cent of profit in it. And I speak of whisky being poisonous in the sense that it is a habit-forming drug.

Senator GIBSON. That situation arises out of the law in a particular State. Where you have a State liquor control and the State sells it, it does not permit advertising.

Mr. LEVER. Are there specific States in the Union, Mr. Chairman, where advertising is forbidden of liquor?

Senator GIBSON. We do not permit advertising particularly of the sale of liquor in my State. It is all handled by State liquor stores. That is the only fair method of handling the problem.

Mr. LEVER. I merely indicate that the liquor business did not wait to be curbed. They proceeded to sell liquor the moment it was legalized, and consequently used every means to sell liquor.

Senator GIBSON. I quite agree with you on that proposition.

Mr. LEVER. Senator Copeland's bill (S. 5) has omitted the following specific requirements for adequate food and drug legislation:

1. The requirement for complete disclosure of formulas on the label.
2. The licensing of medicine manufacturers. (States require licensing of pharmacists—why not drug manufacturers?)
3. That palliatives be compelled to state on the label that they are not cures.
4. The registration of the formulas of cosmetics.
5. Provisions for setting up grades for food stuffs, canned or otherwise.
6. The outright banning of drug advertising for those diseases in which self-medication is dangerous.
7. Provisions for Government consumer-education and research.
8. Curb unethical and dangerous advertising.

The principal weakness in Senator Copeland's bill is that the authority for defining specific violations of the act is left to the discretion of two committees, to be appointed by the President. Qualifications for serving on the committees are not clearly defined. The bill itself is substantially weaker than the original Tugwell bill and to some degree emasulates the present none-too-vigorous food and drug legislation.

Considerable power is given to the Secretary of Agriculture (he may promulgate orders, fix standards, and so forth) but he must resort to the majority approval of either of the two committees mentioned above before his regulation becomes effective.

I will stand corrected, if that is not the case, gentlemen, because this was written a few days ago and may have been changed during the course of these hearings.

Senator COPELAND. I think that is correct.

Mr. LEVER. The salient points about these committees are that there are no provisions for paying them for their work, nor for research (witness the orphaned county consumers councils, which have been similarly treated). Their powers are seriously circumscribed by the wording of the bill and the qualifications for serving on them are of such a vague nature that proprietary medicine makers themselves might be eligible. Mr. Copeland has provided for a sprinkling of other committees, too, from the "industry," the "pro-

mulgators of advertising," the "public" and so forth—but these have neither power nor funds and consequently need not be taken seriously.

Taken as a whole, the bill is a slight concession to a growing consumers movement rather than a straight consumers' bill. It can be said for it, of course, that it does bring cosmetics and advertising within the purview of the law, and that it allows for factory inspection by the Department of Agriculture. The Committee on Public Health is given powers by regulation to designate the dangerous adulterants or narcotics, and to impose safeguards for their use; to require warning on labels against unsafe dosage for use by children; to regulate the licensing of food manufacturers or packers whose products may be contaminated by bacteria, and to designate the diseases for which drugs may not be advertised as having therapeutic value. The second committee, on food standards, is similarly empowered to fix quality standards and identifications for foods. The bill further requires the formulas or unofficial drugs to be filed with the Secretary (but not made public).

I understand again here that a slight change has since been made. Is it the committee's opinion that it shall be made public?

Senator COPELAND. What particular item do you refer to?

Mr. LEVER. That the formulas of unofficial drugs are to be filed with the Secretary but not made public. That was in the original draft in no. 3. But in these hearings, I understood you to say that now the committee had agreed or intends to agree that it shall be made public.

Senator COPELAND. I do not think that is quite right. You are talking of formula disclosures on page 16. The bill as it is now written says that, line 23, page 16, "in case it is fabricated from two or more ingredients, the name of each active ingredient is to be placed upon it." The thought of that was, and I think you will agree with me, that the average citizen would not be particularly benefited by having the formula placed upon a package. But if he is allergic, if he has an allergy, if he is susceptible to some particular drug, that he ought to have the benefit of knowing what those active ingredients are, so that he will know that there is in this preparation a substance which to him is a poison. Of course, there is a very much discussed question as to how it shall be dealt with. When I was commissioner of health in New York I changed the code there and I put in the law that the formula should be filed with the commissioner of health. I do not know how much value there was in that—I am not sure—but this does require that the active ingredients shall be known.

Mr. LEVER. If you will let me go on, Mr. Chairman?

Senator GIBSON. How much longer will you take?

Mr. LEVER. About 3 minutes, perhaps.

It provides for the setting up of minimum standards of strength for antiseptics, and empowers the Secretary of Agriculture to disseminate information regarding food, drugs, or cosmetics when necessary to protect the public health or to prevent fraud.

But will the committee exercise the powers they have? As a National Cooperative Association we back such a bill only because, with all its limitation, it seems to represent a minimum advance over existing legislation. Just how much of an advance depends on the

interpretation of the courts and their ability to thread their way through the maze of generalities to a specific and clear-cut policy of enforcement.

We recommend:

1. That the membership of the committee include officers of consumers cooperative associations, of State food and drug administrations, and of ethical medical, dental, and similar professional associations, and that funds be provided for their functioning.

2. That it should specifically exclude from the committees anyone in any way connected with industries manufacturing, selling, or advertising foods and drugs for profit.

This subject came up yesterday, gentlemen of the committee, in which it was urged that these committees cannot function properly unless representatives of the industry sit on them, on the grounds that there are technical problems involved, and the committees being composed of other people than the manufacturers themselves or their agents, will not be able to find their way through the technical problems. But what we would have on those committees, as is evidenced by a lot of Government experience, is the very representatives or their like who have testified here for industry, who are lawyers and other people and not technicians and scientists in the real sense of the word.

There are many scientists in the Government service today, much more capable, and in the professional and technical organizations, to represent the consumer's point of view and to state what is safe for the consumer to use.

Senator COPELAND. I feel that I should answer that if I may. The Committee on Public Health consists of five members designated by the President with a view to their distinguished scientific attainment and interest in public health with respect to food, drugs, and/or cosmetics, and without regard to their political affiliation. The food provision is for a committee consisting of 7 members, 3 of whom shall be selected from the public, 2 from the food producting, processing, manufacturing, and distributing industry, and 2 from the administration, which would mean that you would have 3 from the public and 2 from the administration who certainly would represent the public so that 5 of the 7 might be called persons representing the public, and that was the intention of the committee.

Mr. LEVER. It gets down, Dr. Copeland, to a definition of the term "public" as it is applied to this particular section of the bill.

Senator COPELAND. I know, but can't you trust the President? We have to trust somebody. These persons, you know, are selected by the President and without regard to political affiliation. You have to place responsibility somewhere, and while I sometimes disagree with the present President, I am certain that he would be honest in his choice of men to represent the public.

Mr. LEVER. I was thinking, Mr. Chairman, that in the light of the bill being intended as a protective measure for the consumer, that the term "consumer" would more clearly define the intent of the bill than the term "public."

Senator COPELAND. Why not say "the consuming public"? I would not object to that.

Mr. LEVER. 3. That complete disclosure of formulae to consumers be mandatory.

4. That medicine manufacturers be licensed.

5. That cosmetics formulae be registered.

6. That provisions be made for setting up grades for all foodstuffs.

7. Curb advertising to a truthful statement of the use and limitations of the product in question and that it must be positively informing.

These provisions would remedy the seven most serious omissions of the bill.

In conclusion, speaking not only as a representative of a consumers' cooperative movement, but as one who has spent years studying the desires and wants of the workers, farmers, and professional people of the country as consumers, I am forced to predict that unless a strong food and drug bill is passed at the present session of Congress, consumers will continue to organize not only in self-protection, but to exterminate altogether these purveyors of poison for profit. The consumers' patience has been stretched to the breaking point. Half-way measures will no longer satisfy their growing consciousness of that which they have a right to expect from their Government.

As evidence that we speak from experience, that our recommendations are perfectly possible of accomplishment, we hereby attach a brief exhibit composed of the latest issue of the Consumers Defender, the official publication of our cooperative association, the technical section of which describes many commodities and which gives their formulae as well as the limitations of their use.

In addition, you will find a brief exhibit of the labels appearing on the products described, with the formula on each. This substantiates our claim that such practice is possible for the consumers protection. There is, however, a fly in the ointment, to be sure, which is that we must take the profit out of them and distribute them through consumers' cooperative organizations to meet the consumers' needs and under their own ownership and control, rather than leave them in the hands of the sellers whose primary interest is to derive as much profit from them as possible irrespective of the consequences to the ultimate consumer.

In conclusion, Mr. Chairman, I merely wish to state that on page 24, lines 12 to 15, if I understood you correctly, you agreed with some one here at the hearings that it would be advisable to leave out these few lines in which it says—

as well as any other disease perilous to the life of the individual or to the public health which may be added to this list by regulations as provided by sections 701 and 703.

The thing that we are afraid of is that if this is left out, when new diseases are developed, and the science is growing, it will be necessary to amend the law in order to include regulations for the control of new diseases. It takes time to do that, naturally, but in the meantime the sellers of drugs will have invented new ones or the old ones under new labels with tremendous claims that they are applicable to the new diseases, and for the protection of the ultimate consumer,

gentlemen of the committee, I think it would be highly advisable to leave the original in the form as at present in print no. 3.

Thank you.

EXHIBIT ATTACHED TO TESTIMONY OF E. J. LEVER

LIQUIFYING CLEANSING CREAM (8 OUNCES NET)

Liquefies instantly when applied. For removing dirt and cosmetics. Made of sun-bleached beeswax, mineral oil, hazel-nut oil, distilled water, and perfume. For members of Cooperative Distributors, Inc., 30 Irving Place, New York.

COLD CREAM (8 OUNCES NET)

For cleansing and for removing make-up. Made of sun-bleached beeswax, mineral oil, hazel-nut oil, borax, distilled water, and perfume. For members of Cooperative Distributors, Inc., 30 Irving Place, New York.

TINCTURE GREEN SOAP (8 OUNCES NET)

For mild cases of dandruff. Do not apply directly to hair. Mix with water for shampoo. U. S. P. formula: 160 cc. soft soap; 5 cc. oil of lavender; ethyl alcohol to make 8 ounces. As first aid for cuts and wounds. Cooperative Distributors, Inc., 30 Irving Place, New York.

PERSPIRATION SUPPRESSOR (4 OUNCES NET)

A 15-percent solution of aluminum chloride. Especially for use in armpits. First rinse with water and dry. Apply solution with swab of cotton. Pat on skin slightly; do not rub. Allow to dry before dressing. First application—two or three successive nights before retiring. Repeat semiweekly or as required. If skin is particularly tender, dilute with equal quantity of water. These directions approved by the American Medical Association. Cooperative Distributors, Inc., 30 Irving Place, New York City.

TISSUE CREAM (8 OUNCES NET)

For lubricating the skin after cleansing. Made of sun-bleached beeswax, lanolin, cocoa butter, mineral oil, borax, distilled water, and perfume. For members of Cooperative Distributors, Inc., 30 Irving Place, New York.

FOUNDATION CREAM (8 OUNCES NET)

For use as a powder base. Made of pure stearic acid, glycerin, potassium carbonate, mineral oil, distilled water, and perfume. Contains no soap. For members of Cooperative Distributors, Inc., 30 Irving Place, New York.

TOOTH POWDER

Made of sodium perborate, 25 percent; castile soap, 1 percent; precipitated chalk, 74 percent. For members of Cooperative Distributors, Inc., 30 Irving Place, New York.

Senator GIBSON. Mr. John S. Hall.

STATEMENT OF JOHN S. HALL, REPRESENTING THE NATIONAL MANUFACTURERS OF FLAVORING EXTRACTS, THE NATIONAL MANUFACTURERS OF FRUIT AND FLAVORING SYRUPS, AND THE NATIONAL MANUFACTURERS OF SODA WATER FLAVORS

Mr. HALL. I have prepared a statement, but I just want to discuss one specific reference in the bill.

Senator GIBSON. You understand the situation with respect to this committee: That we are simply to report this testimony back to the

full committee, so it does not make any difference whether you file a brief or read the statement. It is a good deal better to file the brief, because it all goes back to the full committee.

Mr. HALL. I just wanted to discuss with Senator Copeland, if I may, the amendment in section 302 K. We are particularly interested in paragraph K appearing in section 302.

This is the first time this section has appeared in the bill, and you have heard the testimony from representatives from the confectionery, the bakery, and the ice-cream industry, and we do not see how it is capable of carrying it into force and effect. If that section related only to packaged foods, we would have no objections, but in a lot of the industries wherein it is sold from bulk, it would be very hard to carry into effect.

Senator COPELAND. Are you going to be quite specific now? Do you want to strike out paragraph K entirely?

Mr. HALL. Yes; that is our recommendation.

Senator COPELAND. Short of that, what should be done?

Mr. HALL. The only alternative that I would know would be to amend chapter 2 in reference to terms and definitions, and specifically provide what flavors are and what spices are. We find several references to the use of spices and flavors, and they certainly ought to be designated some way. The confectionery industry they use nothing but artificial flavors. It is impossible to use the natural flavors, and in the ice-cream industry, even insofar as vanilla is concerned, they use vanillin.

Senator COPELAND. And a great many of them are synthetic?

Mr. HALL. Yes; practically all of them. In the bakery industry it is the same way. Up to the present time they have not found any method to use the natural flavor. They will bake out or they will freeze out, and that is what they have been using all the time.

Senator COPELAND. It does not prohibit the use of these artificial flavors.

Mr. HALL. But you have got to declare it on the label.

Senator COPELAND. You are from Chicago, aren't you?

Mr. HALL. Yes.

Senator COPELAND. I saw this United Press dispatch from Chicago, dated February 20:

> An 8-year-old girl was dead today as the result of eating cheap candy colored with a poisonous dye.
>
> Her 5-year-old brother is seriously ill in the county hospital.
>
> Physicians said the children undoubtedly were victims of aniline dyes, used instead of harmless vegetable coloring in the candy, which was bought a week ago. Samples of the candy were sent to the coroner's chemist for analysis. The girl is Mary Fudala. Her brother, John, may die, physicians at the hospital said.

Of course, that is a newspaper story and I cannot vouch for it.

Mr. HALL. In reference to that, Senator Copeland, we have no way of controlling doctors from going out with statements of that kind and character, but I will say this, that during the period of time that we have represented the National Confectioners Association, which was for a period of some 20 years, I myself personally have investigated over 50 cases where children were presumed to have died from the use of color or flavor in candy, and in no case has it ever been substantiated.

Senator COPELAND. Do you know about this case?

Mr. HALL. No; it has not been referred to me, Senator Copeland, but we have run down similar cases, and from our investigation, never did they connect up the candy with the death of the child. It was some other causes, or the children were at parties and they may have eaten some other things. They may have had other kinds of food, canned foods, etc., but never yet has it ever been traced definitely to candy. We have no way of controlling physicians that go out that way, and they will do it. I just had a case where some physician, I believe in Vermont, went on record that a child died after drinking two bottles of imitation extract.

Senator COPELAND. They do not drink alcohol.

Mr. HALL. And in that case later on it was proven that the child had died from diabetes.

Senator COPELAND. Have you a specific recommendation to make regarding the definition that might be included in the bill? I take it from what you say that you want subsection K stricken from the bill.

Mr. HALL. Yes.

Senator COPELAND. We will make a note of it.

BRIEF OF JOHN S. HALL, GENERAL COUNSEL FOR THE FLAVORING EXTRACT MANUFACTURERS' ASSOCIATION OF THE UNITED STATES, NATIONAL ASSOCIATION OF MANUFACTURERS OF FRUIT AND FLAVORING SYRUPS, AND NATIONAL MANUFACTURERS OF SODA WATER FLAVORS

Mr. HALL. Mr. Chairman, my name is John S. Hall, and I am general counsel for the Flavoring Extract Manufacturers' Association of the United States, the National Association of Manufacturers of Fruit and Flavoring Syrups, and the National Manufacturers of Soda Water Flavors. The members of the Flavoring Extract Manufacturers' Association of the United States consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution, and sale of packaged food products, flavoring extracts, spices, common household remedies, and patent and proprietary preparations. All of the aforesaid products are sold for manufacturing and household purposes. The members of the National Association of Manufacturers of Fruit and Flavoring Syrups consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution, and sale of soda fountain fruits, flavors, and sirups intended for use in the dairy, ice cream, confectionery, soda fountain and still beverage industries. The members of the National Manufacturers of Soda Water Flavors consist of manufacturers engaged in the manufacture, production, preparation, packing, distribution and sale of soda water flavors and concentrates intended for use in the still and carbonated beverage industries. All of the members of the various associations which I represent are vitally interested in the proposed revision of the Federal Food and Drugs Act of 1906. They have been represented at all conferences and hearings held by the United States Department of Agriculture and the various Senate committees, and have recommended such changes as they deem advisable in the enforcement of any proposed revision of the Federal Food and Drugs Act of 1906 for the protection of the consuming public, and also for their protection as manufacturers of products coming within the provisions of the bill.

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I wish to reiterate, as set forth in my statements at former hearings held on this bill, the profound wisdom as exemplified by the author of the Federal Food and Drugs Act of 1906 when said bill was considered by Congress at that time wherein Senator Heyburn (Congressional Record, vol. 40, pt. 3, p. 2721) stated:

"This bill fixes no standard upon anything; it authorizes no officer to fix any standard. It provides that the courts, and the courts alone, may determine whether or not an article is contraband under the provisions of this act. The object in avoiding any possible construction that might be held to be fixing a standard was that the bill might never come to conflict with the pure-food legislation of the various States. The States have established different standards, and they have a right to do so. Inasmuch as those standards vary, it would be impossible for an act of Congress, a general law, to avoid some conflict with some of those State laws if you should undertake to fix standards."

There is a vivid contrast between the wording of the present Federal Food and Drugs Act of 1906 and the proposed amendments now contained in S. 5. In general, it is the concensus of opinion of the members of the associations I represent that the Federal Food and Drugs Act of 1906 be brought to date, but in so doing efforts should be made to retain the established precedents heretofore approved by our courts. The aforesaid principles are not carried into effect in S. 5, but on the contrary we find that broad and arbitrary power is placed in the hands of the Secretary of Agriculture. The long controversial question relating to multiple seizures is not clarified, and the present wording relating to multiple seizures is not clarified, and the present wording relating to multiple seizures practically places no restrictions on the United States Department of Agriculture.

The United States Secretary of Agriculture is granted broad and arbitrary powers in promulgating legal definitions and standards for the manufacture, production, and sale of articles of food. It is our contention that this power ought not to be placed in the hands of the Secretary of Agriculture, but ought to be specifically set forth in the law and not left to departmental regulations. Control over the advertising of food, drugs, and cosmetics is intended to be placed in the hands of the United States Department of Agriculture, which power heretofore was confined to the Federal Trade Commission. It is our recommendation that this practice be continued, and the Federal Trade Commission clothed with the necessary power to exercise control over the advertising of food, drugs, and cosmetics.

It is our recommendation that chapter 2, definitions of terms, be amended to include a definition of the term "spices or flavors." Throughout the bill several references are made to spices and flavors, and therefore, it is our recommendation that the following provisions be added:

"The term 'spices' includes all aromatic vegetable substances used for the seasoning of food. They are clean, sound, and true to name, and from them no portion of any volatile oil or other flavoring principle has been removed.

"The term 'flavors' includes all sapid and odorous principles derived from an aromatic plant or part of the plant, together with products synthetically made in simulation thereof, and conforms in name to the plant used in its preparation, or plant of which it is in imitation of."

Chapter 3, section 301, section (a), reads as follows:

"3. If it consists in whole or in part of any filthy, putrid, or decomposed substances or if it is otherwise unfit for food."

Under the aforesaid provision the Secretary of Agriculture would be the sole arbiter regarding all foods that are to be considered otherwise unfit for food. No reasonable interpretation is provided and the Secretary of Agriculture is sole arbiter as to what foods are unfit for human consumption. It is our recommendation that the aforesaid reference be deleted from the bill.

Section 301, Adulterated Food (b) (4), reads as follows:

"(4) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or create a deceptive appearance."

We object to the inclusion of the words "or create a deceptive appearance." No reasonable interpretation is provided, and again the Secretary of Agriculture would be sole arbiter as to what creates a deceptive appearance. Other provisions contained in this section cover practically all known trade abuses, yet a food is deemed to be adulterated if it creates a deceptive appearance be it the color or the container in which it is sold. It is our recommendation that the above reference be deleted from the bill.

Section 302, Misbranded Food (a), reads as follows:

"(a) If its label is false or misleading in any particular.:"

We object to the use of the words "in any particular." The use of the words "in any particular" places in the hands of the Secretary of Agriculture arbitrary power and authority and he is sole arbiter of what is false or misleading, and the sole arbiter of the labeling of all foods as to whether or not said label is false or misleading in any particular. It is our recommendation that the words "in any particular" be deleted from the bill.

Section 302 (d) reads as follows:

"(d) If its container is so made, formed, or filled as to mislead the purchaser."

Under the aforesaid section the Secretary of Agriculture is sole arbiter as to whether or not all packaged foods in a container is made, formed, or filled as to mislead the purchaser. It is our recommendation that this section be amended to read "if its container is so made, formed, or filled so as to evidence an intent to mislead the purchaser."

Section 302 (e) reads as follows:

"(e) If in package form it fails to bear a label containing (1) the name and place of business of the manufacturer, packer, seller, or distributor; and * * *"

The present Food and Drugs Act of 1906 only requires the name of the manufacturer, packer, seller, distributor, and not the place of business. It is our opinion that the requirement that the place of business of the manufacturer be stated on the label will have a tendency to bring about sectional distinction and un-American disparities. It is our recommendation that the words "place of business" be deleted.

Section 302 (f) reads as follows:

"(f) If any word, statement, or other information required on the label under any provision of this Act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily understood by the purchased and user of such article under customary conditions of purchase and use, due consideration being given to the size of the package."

We object to the inclusion of the aforesaid subparagraph as the Secretary of Agriculture would be sole arbiter as to the manner and method packaged food products are to be labeled. It is our recommendation this reference be deleted.

Section 302 (g) reads as follows:

"(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by sections 303, 701, and 703, and (1) it fails to conform to such definition and standard, or (2) its label fails to bear the name of the food prescribed in the definition and standard, and if so required by such regulations when such definition and standard permits optional ingredients other than spices, flavors, and coloring, the common names of such optional ingredients as are present in such food."

We most strenuously object to this subparagraph, as it would make the Secretary of Agriculture sole arbiter as to definitions and standards of identity and definitions and standards of articles of foods. We further object to the inclusion of this subparagraph, as in our opinion it is almost impossible to establish definitions and standards of identity or quality of fabricated foods, and in many instances the structure of fabricated foods differs in various localities. You will note that under this subparagraph (2) spices, flavors, and coloring are not considered optional ingredients, and, therefore, the common name of the aforesaid products may be stated as containing "spices, flavors, and coloring." We, therefore, as aforesaid, recommend that the definitions provided for under chapter 2 include definition of the term "spices, flavors, and coloring." It is our recomendation this subparagraph be deleted.

Section 302 (h) reads as follows:

"(h) If it purports to be or is represented as a food for which a standard of quality or fill of container has been prescribed by regulations as provided by sections 303, 701, and 703, and its quality or fill falls below such standard of quality or fill of container and its label fails to bear a statement, in such manner as the regulations specify, showing that it falls below such standard of quality or fill of container."

We object to this provision as it would require additional uniformitive information on labels regarding the fill of containers, which information would in many cases be of no value to the purchasing consumer.

Section 302 (i) reads as follows:

"(i) If it is not subject to the provisions of paragraph (g) of this section and its label fails to bear (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient in order of predominance by weight; except that spices, flavors, and colorings, other than those sold as such, may be designated as spices, flavors, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of subdivision (2) of this paragraph is impracticable because of normal variations in ingredients, or their quantities, usual to good manufacturing or packing practice, exemptions as to packages of asserted food shall be established, and reasonable variations from the stated order of such ingredients shall be permitted, by regulations promulgated by the Secretary; *And provided further*, That exemption to compliance with the requirements of subdivision (2) of this paragraph is given to such foods where the common or usual name of each ingredient has been filed with the Secretary in accordance with regulations promulgated by him by regulations promulgated by the Secretary."

The aforesaid provision places in the hands of the Secretary of Agriculture broad power to require complete formula disclosure on all proprietary foods. We wish to call particular attention to the fact that no provision under this section is made for the manufacture and sale of proprietary foods sold under a distinctive name. It is our recommendation that this section be amended to provide that "*Provided, however*, That nothing in this section shall be construed to prohibit the manufacture and sale of articles of food sold under a distinctive name which are not in imitation of another food." It is our recommendation this reference be deleted.

Section 302 (k) provides as follows:

"(k) If it bears or contains any artificial flavor, artificial color, or chemical preservative and it fails to bear a label stating that fact."

We object to the inclusion of this section in the act. This is the first time that it has been attempted to foist this requirement upon the food industry. You have heard representatives of the bakery, ice cream, and confectionery industry unqualifiedly go on record that it is incapable of enforcement, and it would have the tendency to cause great injury to the respective industries. We would have no objections to the aforesaid section being confined to packaged foods, but in the bakery industry where bakery goods are sold on sight and in the ice cream and confectionery industries where the finished products are sold from bulk to the consuming public it is absolutely incapable of enforcement. It is our recommendation this reference be deleted.

Section 303, definitions and standards for food, provides for the establishing are sold from bulk to the consuming public it is absolutely incapable of quality and/or fill of container.

We object to the broad powers granted to the Secretary of Agriculture to fix, establish, and promulgate legal definitions and standards of identity, also standards of quality and fill of containers for articles of food. Under the aforesaid provision the Secretary of Agriculture would be sole arbiter, and it is our recommendation that this entire section be deleted.

Section 401, adulterated drugs, (a) (1), provides that a drug shall be deemed to be adulterated "(a) (1) if it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof."

It is hard to reconcile the classification of a drug as being adulterated in the event the advertising thereof is dangerous to health. The Secretary of Agriculture would be sole arbiter as to the facts and determine in what cases advertising of any drug is to be classified as being adulterated and therefore dangerous to health. I also wish to call attention to the fact that in the event the advertising of a drug did not meet with the approval of the Secretary of Agriculture under rules and regulations so promulgated under the extraordinary power granted in section 711, seizures, said drugs would be subject to multiple seizures.

Section 402, misbranded drugs, provides that a drug shall be deemed to be misbranded "(a) if its labeling is false or misleading in any particular. Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion."

We object to the broad power granted to the Secretary of Agriculture to determine as to whether or not the labeling of a drug is false if in every particular of such representation it is not sustained by demonstrable scientific facts or substantial medical opinion. There is no reasonable interpretation for the words "in every particular", and this would make the Secretary of Agriculture sole arbiter.

Section 402 (b) (1) reads as follows: "The name and place of business of the manufacturer, packer, seller, or distributor:"

The present law does not require the place of business of manufacturers of drugs to be declared on the label, and in our opinion would not add to the protection of the consuming public.

Section 402 (c) reads as follows: "(c) If any word, statement or other information required on the label to avoid adulteration or misbranding under any provisions of this act is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily intelligible to the purchasers and users of such articles under customary conditions of purchase and use."

We object to the inclusion of the aforesaid subparagraph, as the Secretary of Agriculture would be sole arbiter as to the manner and method packaged food products are to be labeled.

Section 402 (d) relates to the use of certain narcotic and hypnotic substances and requires that the preparations containing the same be labeled "Warning—May be habit-forming." We object to the use of the words "or any other narcotic or hypnotic substance which has been designated as habit forming by regulations as provided by sections 701 and 703." The aforesaid language would permit the Secretary of Agriculture to include such other substances not specifically mentioned in this section.

Section 402 (e) reads as follows: "(e) If it is not designated solely by a name recognized in an official compendium and its label fails to bear (1) a common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients the names and quantity or proportion of each active ingredient: *Provided*, That exemption to compliance with subdivision (2) of this paragraph is given in such cases where the name, quantity, and proportion of each active ingredient is filed with the Secretary in accordance with regulations promulgated by him."

Our objection to the inclusion of the aforesaid section is that in case any preparation is fabricated with two or more ingredients the name and quantity or proportion of each active ingredient must be stated on the label which places in the hands of the Secretary of Agriculture authority to require complete formula disclosure.

Section 402 (f) relates to complete and adequate directions of the use of all packaged drugs. We object to the placing of such broad power with the Secretary of Agriculture, who is the sole arbiter as to what is adequate directions for use.

Section 502 relates to the misbranding of cosmetics, and I wish to particularly point out that no provision is made for the Secretary of Agriculture to promulgate regulations regarding the standard of identity, nor reasonable standards of quality or the fill of containers for the manufacture, production, and sale of cosmetics. There is no reason why standards of identity, standards of quality, and fill of containers should be provided for foods and not for cosmetics, as there is no comparison between the number of foods on the market and the number of cosmetics.

Section 601. False advertisement relates to the advertising of food, drugs, and cosmetics which may be deemed to be false if it is false or misleading in any particular relevant to the purposes of this act. We object to the power granted to the Secretary of Agriculture to assume control over the advertising of food, drugs, and cosmetics and recommend that this power be granted to the Federal Trade Commission. During the past 5 years we have had a number of cases before the Federal Trade Commission relating to the proper advertising of articles of food, and heretofore have been well satisfied with the decisions rendered. They have not always agreed with our contentions, but nevertheless we have felt that we were given a free and impartial hearing. Several of the former speakers have stated that in their opinion the question of advertising of foods, drugs, and cosmetics should be allocated to the Department of Agriculture in view of the fact that they have men specially trained in this field of endeavor. I can hardly concur in their opinion, and I am certain that the aforesaid principle should not be extended to judges nor

juries called upon to decide any difference in opinion between the officials of the Department of Agriculture and manufacturers especially under our present judicial system, and it is further my opinion that a distinct agency such as the Federal Trade Commission ought to be designated to pass upon the question as to the proper labeling of foods, drugs, and cosmetics.

Section 701 (a). General administrative provisions, specifically provides that the Secretary of Agriculture shall have power and authority to promulgate regulations for the efficient enforcement of this act. This section is, however, further supplemented by section 703 which relates to the public health and food standards committee. Therefore, it is necessary to consider both sections together. Section 703 provides for the creation of a committee on public health, and a committee on food standards, which is granted certain powers to conduct hearings and make recommendations to the Secretary of Agriculture. However, no provision is contained providing that the recommendations of the aforesaid committee be accepted by the Secretary of Agriculture, and therefore, in the final analysis the power and authority to promulgate regulations for the enforcement of the act rests entirely in the hands of the Secretary of Agriculture. It is our recommendation that said sections 701 and 703 be deleted from the bill.

Section 707. Factory inspection relates to the power and authority granted to the Secretary of Agriculture under the guise of the protection of public health to enter into any factory, warehouse, or establishment in which food, drugs, and cosmetics are manufactured, processed, packed, or held for shipment in interstate commerce, and to inspect such factory, warehouse, establishment, or vehicle and all equipment, finished and unfinished materials, containers, and labels used or stored. Our objections to this section is that regardless of the financial hazards involved manufacturers of foods, drugs, and cosmetics would be compelled to at the arbitrary discretion of the Secretary of Agriculture submit to inspection of their plant under the guise that public health and welfare is involved. It is our recommendation that this entire section be deleted from the bill.

Section 711 relates to seizures, and in view of the fact that this is an extraordinary action it should be confined only to food, drugs, and cosmetics involving danger to health or extreme cases of deception. The present wording of the law provides that any article of food, drug, or cosmetic that is adulterated or misbranded when introduced or while in interstate commerce, etc., may be seized at any time by libel. In all cases wherein probable cause exists the aforesaid products are adulterated and therefore dangerous to health and subject to seizure by the chief of station or employees.

Section 711, subparagraph (g), provides that the manufacturer, producer, packer, seller, or distributor shall be privileged to secure a temporary or permanent injunction regarding multiple seizures. We object to the broad power granted to the Secretary of Agriculture regarding such extraordinary action, and it is our recommendation that this section be amended to provide for hearings or other corrective methods before seizure can be made by the Secretary of Agriculture or employees acting under his direction, and furthermore the burden be placed upon the Secretary of Agriculture to estop the aforesaid manufacturers in the continuation of the shipment of said products by court order.

Section 712. Injunction proceedings: (a) Provides that in order to avoid multiplicity of criminal prosecutions or libel for condemnation proceedings, the district courts of the United States are hereby vested with jurisdiction for cause shown to restrain by injunction, temporary or permanent, any person from the repetitious introduction and shipment of adulterated and misbranded food, drugs, or cosmetics, also false advertising thereof. We object to the broad power granted to the Secretary of Agriculture, which clothes him with power to estop the sale of any of the aforesaid products by temporary injunction before trial of the issues. The aforesaid power tends to undermine the basic principles of our Constitution, which specifically provides that no one shall be deprived of this property without due process of law.

Section 717 provides that the act shall become effective 12 months after the date of approval. It is our recommendation that in the event of the passage of this bill the act become not effective for a period of at least 2 years after passage.

In conclusion, I wish to state in behalf of the members of the association I represent that they have continuously cooperated with the President in his efforts to revive American commerce and the so-called "depression." We have

been very much a part of the "new deal", but it is the consensus of opinion of the members of our association that this proposed legislation is a bad deal and that it will throw the food, drug, and cosmetic industries into a chaotic condition for sometime to come. You will note in my opening statement that I referred to the statement of Senator Heyburn during the consideration of the Federal Food and Drugs Act of 1906, and specifically pointed out that at that time much consideration was given to the food manufacturers, in view of the existing food and drug laws of the various States. During the past 25 years the manufacturers of foods and drugs have by cooperation with the Federal and various State food officials attempted to bring about uniformity in the enforcement of the Federal Food and Drugs Act of 1906 and the various State food and drug laws.

If this present bill is passed granting to the Secretary of Agriculture such tremendous power regarding the regulation of the food, drug, and cosmetic industry we will immediately find thereafter every State food and drug official will demand that the same wide and arbitrary powers alloted to the Secretary of Agriculture be duplicated in their person. This is a major problem insofar as the food, drug, and cosmetic industries are concerned, and it is therefore our recommendation that any legislation recommended by this committee should contain specific references in the law, that is to say, that the law itself ought to specifically set out standards of identity, standards of quality, and fill of container of all food, drugs, and cosmetic. The law should not by its vague and uncertain language be left to interpretation by the Secretary of Agriculture to determine the intent and purposes of the law, and issue such regulations as he deems necessary for the enforcement of the law.

It is, therefore, our recommendation that this subcommittee give serious consideration to the Meade bill, H. R. 3972, pending before the House of Representatives. The Meade bill in the opinion of our members revises and amends the present Federal Food and Drug Law to bring it down to date. It retains as much of the existing law as possible and at the same time broadens its scope. It continues in force and effect the precedents and court decisions as established during the past 25 years. The Meade bill does not place in the hands of the Secretary of Agriculture indefinite and broad powers to promulgate legal definitions and standards regarding the manufacture and sale of food, drugs, and cosmetics.

The Meade bill continues in effect the control of advertising in the hands of the Federal Trade Commission, and it is our opinion that advertising of all industrial activity should be allocated to the same agency. The Meade bill furthermore specifically provides in the law itself what are to be considered violations thereof so that manufacturers, producers, sellers, and distributors may become familiarized with the law and govern their acts accordingly.

We wish to take this opportunity of extending our sincere appreciation for the careful consideration this committee has given to this important matter, and it is our hope that a compromise bill will be recommended by this subcommittee so that the Senate Committee on Commerce will report out a bill that is satisfactory to all interested parties.

Senator GIBSON. Mr. Philip.

STATEMENT OF W. BRUCE PHILIP, RETAIL DRUGGIST AND COUNSELOR AT LAW

Mr. PHILIP. My name is W. Bruce Philip. I am a retail druggist and counselor at law.

Senator GIBSON. That is quite a combination.

Mr. PHILIP. I respectfully offer to the chairman of the committee for consideration in lieu of S. 5, or in parts in lieu of parts of S. 5, a food and drug bill that I have prepared. This bill differs from all bills introduced, both in last session and in this session, inasmuch as it is an amended food and drug act; in other words, the present act has been taken and amended instead of being rewritten. A large number of the witnesses both last year and this year have stated that

they thought the food and drug act should be amended and not rewritten. Therefore this bill was so prepared.

May I state that this bill, I think, has a unique and interesting history. It was prepared after a careful review of all bills presented at the last session of Congress and also after a reading of the testimony. It was prepared in a way that those that went over the bill could clearly understand the additions to the present Food and Drug Act. The Food and Drug Act was taken and all additions to the present act were underlined. All parts of the present Food and Drug Act that were to be deleted were put in brackets, so that those that went over the bill had before them the wording of the act as well as the additions and deletions.

This bill was sent into every State in the Union, and to the secretaries of all the State pharmaceutical associations, and a copy was left with Senator Copeland. I received a very courteous reply to that communication. It was left with the food and drug authorities and given to many of the officers of the national associations.

Before Congress convened in January I received a great many criticisms and suggestions. These were all carefully considered and many of them were incorporated in the bill as I have it now before you.

Senator GIBSON. Will you submit that for the record?

Mr. PHILIP. I will not read it, but I will gladly submit it.

(The bill referred to is as follows:)

A BILL To amend the Food and Drugs Act of June 30, 1906, as amended, to prevent the manufacture, shipment, and sale of adulterated or misbranded food, drugs, and cosmetics; to prevent the false advertising of food, drugs, and cosmetics; and to regulate traffic therein

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That the Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for the regulating therein, and for other purposes", approved June 30, 1906, as amended, is hereby amended in title and in the several sections thereof to read as follows:

An Act to prevent the manufacture, sale, or shipment of, adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, cosmetics, and drinks; and for regulating traffic herein; and to prevent the false advertisement thereof; and to safeguard the public health; and to protect the purchasing public from injurious deceptions; and for other purposes.

This Act may be cited as the "Federal Food, Drugs, and Cosmetics Act."

SECTION 1. (a) It shall be unlawful for any person within any Territory or the District of Columbia to manufacture any article of food, drug, or cosmetic which is adulterated or misbranded, within the meaning of this Act; or to falsely advertise any food, drug, or cosmetic within the meaning of this Act.

(b) Any person who shall violate any of the provisions of this Act shall be guilty of a misdemeanor, and for the first offense shall, upon conviction thereof, be fined not to exceed $500, or shall be sentenced not to exceed one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not to exceed $1,000, or sentenced to not more than one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

(c) In the case of a gross and willful violation of this Act which has proved to be highly injurious to the public health, the person convicted thereof shall be guilty of a felony, and the penalty shall be a fine of not less than $1,000 nor more than $10,000, or imprisonment for not less than one year nor more than three years, or both such fine and imprisonment.

SEC. 2. (a) The introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia or

from any foreign country, or shipment to any foreign country of any article of food, drugs, or cosmetics which is adulterated, misbranded, or falsely advertised within the United States, within the meaning of this Act is hereby prohibited.

(b) It shall be unlawful for any person to ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country; or to receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country; or for any person who has received to deliver, in original unbroken packages, for pay or otherwise; or for any person to offer to deliver to any other person, any such articles so adulterated, misbranded, or falsely advertised within the meaning of this Act, or for any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated, misbranded, or falsely advertised food, drugs, or cosmetics, or to export or to offer to export the same to any foreign country: *Provided*, That no article shall be deemed misbranded, adulterated, or falsely advertised, within the provisions of this Act, when intended for export to any foreign country, and is labeled on the outside of the shipping package with the words "For Export", and is otherwise prepared or packed and labeled according to the specifications and directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this provision shall not exempt said article from the operation of any of the other provisions of this Act.

SEC. 3 (a). The Secretary of the Treasury and the Secretary of Agriculture shall issue uniform regulations relative to food, drugs, cosmetics, and all advertising thereof, as shall be established in accordance with regulations, which shall be promulgated hereafter as in this section of this Act for carrying out the provisions of the Act, including the collection and examination of specimens of food, drugs, cosmetics, packages, labels, and advertisements thereof, which are manufactured, disseminated, or offered for sale in the District of Columbia or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they have been respectively manufactured, produced, labeled, or advertised; or which shall be received from any foreign country, or intended for shipment to any foreign country; or which may be submitted for examination by the chief health, food, drugs, cosmetics, or advertising officer of any State, Territory, or the District of Columbia; or at any domestic or foreign port through which such product is offered for interstate commerce; or for export or import between the United States and any foreign port or country.

(b) For the efficient enforcement of this Act and to advise the Secretary of Agriculture, there shall be appointed by the President of the United States without regard to political affiliations, four committees, namely:

(1) A committee of seven members on Food Regulations which shall have authority to promulgate, as hereinafter provided, all regulations under this Act concerning food; all of whom shall be qualified as to the food-producing, food-processing, or food manufacturing industry; two of whom shall be appointed from the Food and Drug Administration.

(2) A committee of five members on Drug Regulations which shall have authority to promulgate, as hereinafter provided, all regulations under this Act concerning drugs; all of whom shall be qualified in the drug industry; one of whom shall be appointed from the Food and Drug Administration.

(3) A committtee of three on Cosmetic Regulations; which shall have authority to promulgate, as hereinafter provided, all regulations under this Act concerning cosmetics; all of whom shall be qualified in the cosmetic industry; one of whom shall be appointed from the Food and Drug Administration.

(4) A committee of five on Advertising Regulations, which shall have authority to promulgate, as hereinafter provided, all regulations under this Act concerning advertising, all of whom shall be qualified in the advertising branch of the graphic arts industry; one of whom shall be appointed from the Food and Drug Administration.

(c) The term of office of members of the committees designated in paragraphs 1, 2, 3, and 4 of section 3 (b), as are appointed on the first Food Regulation Committee shall expire at intervals of one year, as shall be designated by the President at the time of their respective appointments: *Provided*,

however, That the terms of those first appointees shall be respectively, one, two, three, four, and five years: *And provided further*, That the two members appointed from the Food and Drug Administration shall serve at the pleasure of the President. The terms of office of the members as are appointed on the Drug Regulations and also on the Advertising Regulations shall expire at intervals of one year, as shall be designated by the President at the time of their respective appointments: *Provided, however*, That the terms of these first appointees shall be respectively one, two, three, four, and five years: *And provided further*, That the one member appointed from the Food and Drug Administration shall serve at the pleasure of the President.

The terms of office of the members as are appointed on the Cosmetic Regulations shall expire at intervals of one year, as shall be designated by the President at the time of their respective appointments: *Provided, however*, That the terms of those first appointees shall be respectively four and five years: *And provided further*, That the one member appointed from the Food and Drug Administration shall serve at the pleasure of the President.

(d) Each committee shall convene at least once a year in the city of Washington, District of Columbia, at a time and place to be designated by its chairman; and each committee respectively shall at such annual meetings elect its own chairman for the ensuing year.

(e) Whenever the Secretary of Agriculture deems that any regulation or the administration or enforcement of this Act should be established, he shall advise the appropriate committee. Only with the approval of a majority of the members shall the committee recommend to the Secretary of Agriculture the proposed regulation. Then the Secretary of Agriculture shall give public notice of the proposal, and of the time and place of a public hearing which is to be held thereon; which hearing shall be held not less than thirty days after the date of such notice. After such public hearing the Secretary of Agriculture is authorized to issue such regulation as shall have been promulgated with the approval of a majority of the members of the respective committee. The authorized regulation so promulgated shall become effective on a date fixed by the Secreetary of Agriculture, which date shall not be prior to ninety days after its promulgation. A regulation may be amended or repealed in the same manner as is provided for its adoption.

(f) Actions by any committee upon regulations proposed for promulgation may be taken by the members thereof acting without convening in meeting. Members of the appropriate committee shall be given due notice of, and may sit with the Secretary of Agriculture or his representative at all such public hearings relating to the functions of their respective committees. The Secretary of Agriculture shall transmit to each member of such committee a transcript of the record of the public hearing held by him.

(g) Each committee on its own motion, or at the request of the Secretary of Agriculture, may advise him of its views on any question concerning the enforcement of this Act.

(h) Hearings authorized or required by this Act shall be conducted by the Secretary of Agriculture, or such officer or employee of the Department of Agriculture as he may designate for the purpose.

SEC. 4. That the examination of specimens of food, drugs, cosmetics, and advertising thereof shall be made in such existing bureau or bureaus of the Department of Agriculture, as may be directed by the Secretary of Agriculture or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated, misbranded, or falsely advertised within the meaning of this Act; and if it shall appear from any such examination that any of such specimen is adulterated, misbranded or falsely advertised within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the manufacturer of such article if known, or if unknown, then the party who caused said article to be introduced into interstate commerce. Any party so notified shall be given an opportunity to be heard under such regulations as may be promulgated according to this Act, and if it appears that any of the provisions of this Act have been violated by such manufacturer or such person who introduced the article into interstate commerce, the Secretary of Agriculture may at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by

publication in such manner as may be prescribed by the regulations promulgated as in section 3 of this Act.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health, food, drug, or cosmetic officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violations, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. (a) That the term "food", as used in this Act, includes all substances and preparations used for or entering into the composition of food, drink, confectionery, or condiment for man or other animal.

(b) The term "drug", as used in this Act, includes:

(1) All medicinal substances and preparations recognized in the latest editions of the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, National Formulary, or in an official supplement thereto: *Provided*, That whenever a drug is recognized in both the United States Pharmacopœia and the Homeopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia;

(2) All medicinal substances, and preparations intended to be used in the cure, mitigation, treatment, or prevention, of disease in man or other animal;

(3) All substances and preparations other than food, including dentifrices, intended to affect the structure or any function of the body of man or other animal;

(4) "All devices", which includes mechanical contrivances for therapeutic use in man, or for the alleviation of pain, either to prevent it or to investigate its presence in man; or for use to remedially affect the structure or any function of the body of man.

(C) The term "cosmetic" as used in the Act includes all substances and preparations intended for application to the person for the purpose of cleansing, improving, preserving, refreshing, and altering by promoting the appearance of some part of the body.

(D) The term "advertisement" includes all statements, oral, written, or by other means publicly disseminated, which turn the attention of others to food, drugs, cosmetics, or another advertisement, and which includes all matter accompanying a sale or distribution of food, drugs, cosmetics, or another advertisement.

(E) The term "package" and the term "original unbroken package" as used herein mean the immediate container of the article which is intended to be delivered to the public for the purpose of consumption.

(F) The term "official supplement" in this Act means an additional issue of but a part of an official compendium which adds to or deletes parts from a prior issue of the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, or of the National Formulary, and which same official supplement is authorized by the agencies as have sponsored such original compendium: *And provided further*, That the "official supplement" is the issue official at the time the drug, medicine, or cosmetic enters into interstate commerce.

(G) The term "label" means any and all statements, brands, tags, designs, graphic matters, or devices pertaining to, and upon or attached to a food, drug, cosmetic, or advertisement thereof; or upon or attached to any and all containers, wrappers, or coverings thereof, pertaining to a food, drug, cosmetic, or advertisement thereof.

SEC. 7. (I) For the purpose of this Act an article shall be deemed to be adulterated:

(A) In the case of drugs:

First. (a) If, when a drug enters interstate commerce under or by a name recognized in the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States, National Formulary, or of an official supplement, it differs in the finished product from the standard of strength, identity, purity, as determined by the test laid down in the United States Pharmacopœia,

Homeopathic Pharmacopœia of the United States, National Formulary, or in an official supplement which is official at the time when the drug enters interstate commerce: *And provided further*, That—

(c) No finished preparation shall be deemed to be adulterated under this provision if, during the process of manufacture, other processes and standards of strength, identity, and purity of materials are used, as are made necessary to meet manufacturing requirements: *And provided further*, That—

1. The finished product so made does not differ in strength, identity, or purity from official strength, identity, and purity: *And provided further*, That—

2. The strength, identity, and purity which exceeds or is lower than the official strength, identity, or purity is plainly stated on the label in juxtaposition to the principal name of the article: *And provided further*, That—

(3) The statement of the strength, identity, and purity on the label of the finished product shall be supplemented with a statement of what is the official strength, identity, or purity of the standard preparation.

Second. (a) If its strength, identity, or purity fall below the professed standard of strength, identity, or purity under which it enters interstate commerce.

(B) In the case of confectionery or ice cream:

(a) If it contains terra alba, barytes, talc, chrome yellow, resinous glaze, or other mineral substances; or poisonous color or flavor; or nonnutritive substance, or other ingredients proved deleterious or detrimental to health; or any vinous, malt, or spiritous liquor or compound of these, or narcotic drug: *And provided, however*, That—

(b) Nonnutritive substance shall not include masticatory substances in chewing gum, nor coloring, flavoring, natural gums, agar-agar, gelatin, and pectin: *And provided further*, That—

(c) This section shall not prohibit the use in confections of a wood handle or a handle made of nonpoisonous material which shall be at least three inches in one of its lineal measurements.

(C) In the case of food:

First. (a) If any substance has been added thereto, mixed and packed with it so as to increase its bulk or weight, or to lower or injuriously affect its quality, identity, or strength.

Second. (a) If any substance has been substituted wholly or in part therefor.

Third. (a) If any valuable constituent has been wholly or in part abstracted therefrom.

Fourth. (a) If it be mixed, colored, powdered, coated, stained, or altered in a manner whereby damage or inferiority is concealed.

Fifth. (a) If it bears or contains any poisonous or deleterious substance which renders it injurious to health, or if it bears or contains any added poisonous or added deleterious substance which is prohibited or which is in excess of the limits of tolerance as may be promulgated by the committee on food regulations: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application which is applied in such manner that the preservative may be removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative is printed on the covering or the package, then the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth. (a) If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

Seventh. (a) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations promulgated by the committee on food regulations.

(D) In the case of cosmetics.

First. (a) If the strength, identity, or purity of a cosmetic fall below the professed standard of strength, identity, or purity under which it enters interstate commerce.

Second. (a) If it bears or contains poisonous or deleterious substances in such quantities as to render it injurious to the user under the conditions of use prescribed in the labeling or advertising thereof, or when used under such conditions of use as are customary or usual.

Third. (a) If it bears or contains poisonous or deleterious substances prohibited, or in excess of the limit of tolerance as promulgated by the Committee of Cosmetic Regulations.

SEC. 8. The term "misbranded", as used herein, shall apply—

(1) To all drugs or cosmetics or articles of food or articles which enter into the composition of food or drugs or cosmetics; or to the package of or label of or literature, which shall bear any statement, design, graphic matter, or device regarding such article; or the ingredients or substances contained therein, which shall be false or fraudulent in any particular; and

(2) To any food, drug, or cosmetic which is falsely branded as to, or which is not branded with, the name and address of the manufacturer, packer, seller, or distributor thereof; and

(3) To any package on which any word, statement, or other information required on the label under provisions of this Act is not prominently placed: *Provided, however*, That—

(a) A drug which is put up at one establishment and is to be labeled at another shall be exempt from the labeling requirements of this Act while in transit from the former to the latter establishment.

(II) For the purposes of this Act, an article shall also be deemed to be misbranded:

(A) In the case of drugs:

First. (a) If it is an imitation of or if it is offered for sale under the name of another article or if it is a simulant of the name of another article.

Second. (1) If the contents of the package as originally put up shall have been removed in whole or in part;

(2) If other contents shall have been placed in such package;

(3) If the package fail to bear a statement on the label of the quantity or proportion of ethyl alcohol, isopropyl alcohol, ethyl ether, morphine, opium, cocaine, codeine, heroin, alpha or beta eucaine, chloroform, cannabis, chloral, bromal, carbromal, paraldehyde, peyote, sulphonmethane, barbituric acid, strychnine, or acetanilid, or derivative or preparation of any such substance contained therein.

Third. If its package or label shall bear or contain any statement, design, graphic matter, or device regarding the curative, remedial, or therapeutic effect of such article or any of the ingredients or substances contained therein, which is (1) false, (2) fraudulent.

Fourth. (1) If, when it is a drug which is in the United States Pharmacopœia, or Momeopathic Pharmacopœia of the United States, or in the National Formularly, or an official supplement, that is liable to deterioration, which will affect its therapeutic or remedial value or keeping quality, there is not a statement on the label which either repeats or substitutes an edited, declarative, plain, and precautionary statement such as my be necessary to warn and to inform the customer.

(2) If, when it is a drug which is not in the United States Pharmacopœia, Homeopathic Pharmacopœia of the United States or National Formularly, or an official supplement, and is in regulations which have been promulgated under the provisions of this Act and which drug is known to deterioration which will affect its therapeutic or remedial value or keeping quality, it has not on the label a plain and precautionary statement such as may be necessary to warn and to inform the consumer.

Fifth. If it is in package form, and the quantity of the contents is not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted; and that tolerances and exceptions as to certain packages shall be established by promulgated regulations made in accordance with the provisions of section 3 of this Act: *Provided, however*, That prescriptions written by licensed physicians, dentists, veterinary surgeons, and other medical practitioners shall be exempt from the misbranding provisions of this Act.

(B) In the case of cosmetics:

First. (a) If the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package.

(C) In the case of foods:

First. If it is an imitation of, or is offered for sale under, the distinctive name of another article, or is a simulant of the name of another article.

Second. If it is labeled, branded, or purports to be a foreign product when it is not.

Third. If the contents of the package as originally put up shall have been removed in whole or in part, and other contents shall have been placed in such package.

Fourth. If it is in a package form, and the quantity of the contents is not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however,* That reasonable variations shall be permitted; and that tolerances and also exceptions as to certain packages, as shall be established by promulgated regulations made in accordance with the provisions of section 3 of this Act.

Fifth. If the package containing it or its label shall bear any statement, design, graphic matter, or device which shall be false or fraudulent in any particular: *Provided,* That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

(a) In the case of mixtures or compounds which may be now or from time to time hereafter may be known as articles of food, under their own distinctive names, and which articles are not an imitation of or are not offered for sale under the distinctive name of another article: If the name is accompanied on the same label or brand with a statement of the name and address of the manufacturer, packer, seller, distributor, or labeler thereof.

(b) In the case of articles labeled, branded, or tagged so as to plainly and prominently indicate that they are compounds of foods, imitations of other foods, or blends of foods, when the word "compound", "imitation", or "blend", as the case may be, is plainly stated and prominently placed in juxtaposition with the name on the package in which it is offered for sale: *Provided,* That the term "blend" as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients which are used only for the purpose of coloring and flavoring: *And provided further,* That nothing in this Act shall be construed as requiring or compelling proprietors, packers, sellers, distributors, labelers, or manufacturers of proprietary foods to disclose their trade formulas of foods, which contain no unwholesome added ingredients, except insofar as the provisions of this Act may require a disclosure to secure freedom from adulteration or misbranding.

Sixth. (a) If it is canned food and the food falls below the standard of quality, condition, and/or fill of container, as promulgated by regulations made in accordance with the provisions of section 3 of this Act for such canned food, and if its package or label does not bear a plain and conspicuous statement, as promulgated by regulations made in accordance with the provisions of section 3 of this Act, which indicates that such canned food falls below such standard.

(b) For the purpose of this paragraph (1) the words "canned food" mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat-food products which are subject to the provisions of the Meat Inspection Act of March 4, 1907, as amended, and except canned milk; (2) the word "class" means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product; (3) from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will promote honesty and dealing in the interest of the consumer may be promulgated by regulations made in accordance with the provisions of section 3 of this Act; (4) from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by regulations made in accordance with the provisions of section 3 of this Act, and which will indicate that such canned food falls below such standard; (5) in promulgating such standards and forms of statements and any alteration or modification thereof, there shall be specified the date or dates when such standards shall become effective, or after which such statements shall be used, and the Secretary of Agriculture shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statement shall be used; and (6) nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods

SEC. 8½. The term "advertisement" as used in this Act is synonymous with the term "advertised" and the term "advertising" as the case demands, and shall include all statements, oral, written, or by other means commercially disseminated, which turn the attention of others to food, drugs, cosmetics, or advertisements thereof.

(D) That for the purposes of this Act and advertisement be deemed to be false—

First. (a) If it is not conformable to fact or if it expresses what is contrary to fact; (b) or when it is made or designed for the purpose of deceiving.

Second. If in the advertisement there is used the term "doctor", or an abbreviation of the term "doctor", and it fails to plainly and prominently specify in full the title, or kind, or specific classification meriting such title.

Third. (1) If in an advertisement there is a testimonial which is not verified by the advertiser who uses it;

(2) If in an advertisement there is a testimonial which is used after the death of a person;

(3) If in an advertisement there is a testimonial the original of which is not dated and sworn to before a notary or other qualified public official;

(4) If the reproduction of a testimonial in an advertisement does not clearly and prominently show its dating;

(5) If a testimonial which is used in an advertisement is not conformable to fact, or if it expresses what is contrary to fact.

Fourth. If it advertises a preparation in which therapeutic or remedial claims are based upon the presence of some drug or ingredients of some drug when in fact such drug or ingredients of such drug are present in minute quantity.

Fifth. If it quotes or refers to a textbook (a) and fails to state the name of the book, name of the author, or, if more than one author, then of the principal author, and the year in which such textbook was published; (b) and fails to mention the year or years when such book was used as a text; and (c) if it quotes a text and fails to quote adequate facts from that text.

Sixth. If in it adjectives or adverbs in the superlative degree are used where such cannot be a conformable fact.

SEC. 9. No person acting in the capacity of a dealer shall be prosecuted under the provisions of this Act for having received or shipped in interstate commerce any food, drug, or cosmetic; and who in good faith sells it when he can establish a guaranty or undertaking signed by the person, who must reside in the United States, and from whom he in good faith received the article of food, drug, or cosmetic, or the advertising copy thereof; and which guaranty or undertaking is to the effect that the same is not adulterated or misbranded within the meaning of the Federal Food, Drugs, and Cosmetics Act. And said guaranty, or undertaking, to afford protection, shall contain the name and address of the person, furnishing such guaranty, and such person shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the person acting in the capacity of a dealer, under the provisions of this Act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act and is being shipped from one State, Territory, District, or insular possession to another for sale, or having been shipped, remains unloaded, unsold, or in original unbroken packages, or if it is sold or offered for sale in the District of Columbia or the Territories or insular possessions of the United States, or if it is imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however,* That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or oherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 10. (A). The Secretary of Agriculture, upon application of not less than 60 per centum of the packers of any sea food sold in interstate commerce,

may at his discretion designate supervisory inspectors to examine and inspect all premises, equipment, methods, materials, containers, and labels used by such applicants in the production of such food. If the food is found to conform to the requirements of this Act, the applicant shall be authorized, in accordance with regulations prescribed by the Secretary of Agriculture, to mark the food so as to indicate such conformity. Services to any applicant under this section shall be rendered only upon payment of fees to be fixed by regulations promulgated according to section 3 of this Act, in such amount as to cover the cost of the supervisory inspection and examination, together with the reasonable costs of administration incurred by the Secretary of Agriculture in carrying out this section. Receipts from such fees shall be converted into the Treasury and shall be available to the Secretary of Agriculture for expenditures incurred in carrying out this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, brand, graphic matter, statement, or other identification devices authorized by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not more than $5,000, or both such imprisonment and fine.

SEC. 10 (B). Notwithstanding the provisions of section 4, the Secretary of Agriculture, shall, before certifying any violation of section 8, (A), Third, 1, 2, "In the case of drugs", in section 8 of this Act, to any United States district attorney to cause any seizure for confiscation by process of libel for condemnation, cause notice to be given to the person primarily responsible for the representations alleged to be in violation of said section 8 (A), Third, 1, 2, and a day to be fixed upon which said person may be heard. No criminal proceeding shall be commenced nor shall any drugs be proceeded against or seized for condemnation on the grounds that the label or package or advertisement of said drugs bear or contain any statement, brand, tag, design, graphic matter, or device regarding the curative, remedial, or therapeutic effect of such article or any of the ingredients or substances contained therein which is false or fraudulent, unless and until the Secretary of Agriculture shall have given the notice and afforded the opportunity for hearing as provided in this section. At such hearing, the person interested may furnish evidence, either by himself or his representative, to justify the representations of therapeutic or remedial value made in or upon such label or package, or both. In the event such person shall refuse or is unable to justify such representations to the satisfaction of the Secretary of Agriculture or to a person designated by the Secretary of Agriculture to hold such hearing, the Secretary of Agriculture shall fix a reasonable time for such person to discontinue such representation or to make changes in or upon the label or package in the manner indicated by him or his representative. After such hearing, the Secretary of Agriculture shall furnish such person a statement or rulings and set forth reasons therefor.

If such person at such hearing shall by proper evidence justify such representations as have been objected to or shall make changes as directed by the Secretary of Agriculture; then the Secretary of Agriculture shall furnish such person with a certificate setting forth the facts and the final adjustment.

In the event of the refusal or failure of such person to conform to directions of the Secretary of Agriculture, or his designate, within the time fixed to discontinue representations or to make changes in the package or label, the Secretary of Agriculture shall at once certify the facts as provided in section 4 of this Act.

Not more than one action against a like drug or article based upon alleged false or fraudulent representations of therapeutic or remedial value shall be pending in the courts of the United States at any one time, nor until after there has been a first adjudication against said drug or article as is misbranded within the meaning of said section 8 (A), Third, 1, 2.

Upon good cause being shown and after due notice being given by the District Attorney that an emergency exists, the judge of the court in which said action has been commenced may enjoin the repetitious introduction in interstate commerce of drugs or articles like the drug or article seized, until such time as the pending cause may be tried.

In the event, after the trial of said single action, there shall have been a final decree or judgment entered in favor of the Government, then further

proceedings in libel for confiscation may be commenced against the drugs or articles complained of and the label, package, or advertisement of which bears or contains like statements, brands, tags, devices, graphic matter, or such, which have been shipped interstate commerce.

The district attorney may apply to the district court in any jurisdiction where such drugs or articles may be found, the label and package of which bears or contains any statement, brand, tag, design, graphic matter, or device, concerning the therapeutic, or remedial value of such drugs or articles or of the ingredients contained therein which is false or fraudulent, upon a showing that an emergency exists and that drastic action in the interests of public health is necessary, and may obtain an order directing the United States marshal to impound such drugs or articles pending further order of the court.

Appeals and other proceedings under this section may be had in accordance with title 12 (c) section 1121 (Judicial Code, Numbered 129).

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of food, drugs, cosmetics, and advertisements thereof, which are being imported into the United States or offered for import, and shall give notice thereof to the owner or consignee. The owner or consignee may appear before the Secretary of Agriculture, and have the right to introduce testimony. If it appear from the examination of such samples, that any article of food, or drug, or cosmetic, or advertisement thereof which is offered to be imported into the United States, is adulterated, misbranded, or false within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States; or if it is of a kind forbidden entry into, or if it is forbidden to be sold, or disseminated, or restricted in sale in the country in which it is made, or from which it is exported; or if it is otherwise falsely labeled or advertised in any respect; then the said article or articles shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any article or articles which are refused delivery, and which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe; in accordance with the provisions of section 3 of this Act: *Provided further*, That pending examinations and decisions in the matter, the Secretary of the Treasury may deliver to the consignee such article or articles on execution of a penal bond for the amount of the full invoice value of such article or articles together with the duty thereon. Upon refusal by the consignee to return such article or articles for any cause to the custody of the Secretary of the Treasury, when they are demanded, for the purpose of excluding them from the country, or for any other purpose, the full amount of the bond shall be forfeited: *And provided further*, That all charges for storage, cartage, and labor on article or articles which are refused admission or delivery, shall be paid by the owner or consignee, and in default of such payment such charges shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States. The term "person" as used in this Act shall be construed to import both the plural and singular, as the case demands, and shall include individuals, partnerships, corporations, companies, societies, and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by an individual, partnership, corporation, company, society, or association, within the scope of his employment or office, shall in each case be also deemed to be the act, omission, or failure of such individual, partnership, corporation, company, society, or association as well as that of the person.

SEC. 13. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

SEC. 14. These amendments shall take effect twelve months after the date of their approval. All provisions of the Federal Food and Drugs Acts of June 30, 1906, as amended (U. S. C., title 21, secs. 1 to 13), not herein amended, are not repealed. All sections of the Federal Food and Drug Act of June 30, 1906, which are herein amended are hereby repealed on such date.

120089—35——20

Mr. PHILIP. I would like to discuss this bill very briefly. One of the real objections to all the bills presented has been the manner of making the regulations. The regulations are made as provided in this suggested bill by committees appointed by the President. Every member of the respective committees is to be trained and qualified in the group that he will make regulations for; that is, the food committees will be qualified as to foods, the drug committee will be qualified as to drugs, and the cosmetic committee will be qualified as to cosmetics, and the advertising committee will be qualified as to the graphic arts. I think there is no question but that people fully qualified can be selected by the President, and they alone after the hearings should be permitted to make the regulations.

There is no question from those that have attended these hearings that there is a wide difference of opinion as to what certain wording in S. 5 means. There is a wide difference of opinion as to how far a regulation will control an industry and either help the consumer or maybe ruin the industry, and I do not believe that anyone that is not qualified can sit on a committee and give the right attention, the right thought, and bring out a correct regulation.

Senator COPELAND. I would like to say, Mr. Chairman, if the witness will permit me, that we had this bill, and found in it much valuable material, and I think when the witness studies our bill carefully he will recognize some of his own language.

Mr. PHILIP. I appreciate Senator Copeland stating that, and I will say further that Senator Copeland I think has been most fair in endeavoring to give all people interested in this legislation attention and consideration as to their suggestions.

What I fear, Mr. Chairman and Senator Copeland, more than anything else, is that if we rewrite this law we are going to face a possible interpretation by the courts as to the language of the law that will not be expected. We are finding here today witnesses coming who did not appear before, that did not understand certain wordings in bill S. 5, and when this bill, or whatever bill becomes a law, passes, you are going to immediately have litigation. You are going to immediately have court interpretations.

Senator COPELAND. You can give up the drug business then to be the counsel.

Mr. PHILIP. I might say, Senator, the worst the bill is the more prospective clients I will have, but I am not talking from that point of view. I am talking because my interest is principally in the retail drug-store owner and his problems. That is why I studied law.

Senator COPELAND. And the public.

Mr. PHILIP. I am interested in the public, but I differ from a great many people. I believe that industry is basically honest. I believe that industry basically will support any fair legislation even if it affected their financial condition. And I believe that industry can give officers and give committees help and will give help in honestly enforcing any law in the interest of the consuming public. I think if you will analyze the witnesses that have sponsored S. 5 you will find that what they want is a food and drug law brought up to date. They want cosmetics and advertising reasonably controlled. And if S. 5 had not been introduced those same people would have supported S. 580, or the Mead bill, or this suggested bill, or any other bill. I honestly do not believe that 98 or 99 percent of the members of organizations that have sent representatives here to approve S. 5 could pass an examination on any bill that has been introduced into the last or this session of Congress as to many of their points. I really respect the consuming public that come here asking for legislation, but that public is not in a position to carefully analyze and interpret the provisions of any of these measures and say definitely just what a court will decide as to their practicability, as to their legality, or as to what we will have. I feel very keenly, Mr. Chairman, that we are considering probably one of the most important bills that is before Congress. And I still feel that instead of rewriting the law we should amend the law, and by amending the law we are going to protect the consuming public more, and we are going to have a better law. We must not forget that the Pure Food and Drugs Act has over 22,000 judgments in its favor. It has suffered comparatively few defeats. It has done a great deal to bring about a better condition as to foods and drugs. And I may differ with some witnesses in this belief. I believe that all industry has helped in being willing to accept the department's interpretations and being willing through their associations to make better conditions for the consumer, because it must be self-evident that the least consumer resistance there is to a preparation the better opportunity for a sale.

May I say in closing as to my personal qualifications for presince 1900, that I have operated a drug store, and still operate it as a co-partner, before the original Food and Drugs Act was passed, and that I have probably handled from ten to twenty thousand preparations that must be labeled or prepared under the Food and Drugs Act. As a counsel I have had cases before both the State and the Federal departments in reference to labeling and adulteration, and that I have served on the legislative committee of both State and national associations during almost this whole period of time.

May I also state in this matter that you must consider we have 48 States, and these 48 States have State Food and Drugs Act, and they must be changed each time the Federal act is changed if we have a uniform enforcement system. And therein lies a danger. If you rewrite the Federal act you are going to have State acts not amended, but rewritten, and there you will have every political power and all the controversies coming in and all the freak legislation that is often adopted when you have a radical change. Therefore, when you amend the Federal Food and Drugs Act you are going to stand the greatest chance of amending in the same way these State Food and Drugs Acts, and you will have a far more uniform and better law, because it is also quite evident that no matter what kind of a Federal Food and Drugs Act you make in the States, we will say, of California, or Texas, or Pennsylvania, or New York, large States, persons can manufacture preparations and sell them within the State without any supervision from interstate commerce.

Senator GIBSON. Is Mr. Harry Noonan here?

(No response.)

Senator GIBSON. Mrs. Robins Gordan.
(No response.)
Senator GIBSON. Mr. Rosenthal?
(No response.)
Senator GIBSON. Mr. Swain?
(No response.)
Senator GIBSON. Mr. Epstein?
(No response.)
Senator GIBSON. Mr. Trafford?
(No response.)
Senator GIBSON. Dr. Fischelis?
(No response.)
Senator GIBSON. Mr. W. P. Johnson.

STATEMENT OF W. P. JOHNSON, REPRESENTING THE NATIONAL AMERICAN WHOLESALE GROCERS' ASSOCIATION

Mr. JOHNSON. My name is W. P. Johnson, the Washington representative of the National American Wholesale Grocers' Association. We represent something near two thousand wholesale grocers scattered throughout the United States. We just want to file a letter stating that we are in full accord with this bill as offered under the committee print no. 3.

(The letter referred to is as follows:)

Mr. Chairman and members of the committee, my name is W. P. Johnson, and I am the Washington representative of National American Wholesale Grocers' Association, the headquarters of which is located at No. 99 Hudson Street, New York City.

Our Association is the result of a union of the old National Wholesale Grocers' Association and the American Wholesale Grocers' Association.

The first official act of the National Wholesale Grocers' Association, which was organized in 1906, was to send to President Theodore Roosevelt, and to Members of Congress its approval of the bill which now is the Federal Food and Drugs Act. For 27 years our association has advocated and promoted the enactment of State food laws prohibiting adulteration and misbranding of foods uniform with the Federal statute. In behalf of National American Wholesale Grocers' Association, representing 1,700 wholesale grocers scattered throughout the United States, I wish to endorse Senator Copeland's bill, known as "Senate 5" in its present form.

Very truly yours,

W. P. JOHNSON,
Washington Representative.

Senator GIBSON. Mr. Rogers?
(No response.)
Senator GIBSON. Mr. Bushon?
(No response.)
Senator GIBSON. Mr. Stevens.

STATEMENT OF HENRY STEVENS

Mr. STEVENS. My name is Henry Stevens. Mr. Chairman, I will take not more than 5 minutes. I am representing myself. As an allergic individual, I wish to comment particularly on section 302, paragraph (i). There has been quite a little loose talk about allergy and the protection of the allergic individual, and I can speak with great conviction on that. Although I am not an allergist, I have given the subject considerable study in the past several years, and have been so unfortunate as to have an allergy clinic in my own home.

This provision exempts from the statement on the label, spices, flavorings, and colors. I would like to call attention to the fact that in the extensive literature on allergy, spices, flavors, and colors are recorded, that is the individual members of spices, flavors, and colors are all recorded as allergens.

Senator COPELAND. As possible allergens?

Mr. STEVENS. As possible allergens, and the individual ones are different. I have a brief list of them, which is as follows: Cinnamon, pepper, caraway seed, ginger, horseradish, paprika, poppyseed, vanilla, mint, garlic, nutmeg, and mustard. This particular author states that in any complete examination of an allergic individual certainly cinnamon, pepper, and mustard should be tested.

Senator COPELAND. Did he limit it to those three?

Mr. STEVENS. That particular allergist did.

Senator COPELAND. Who is the authority for that?

Mr. STEVENS. S. M. Feinberg. I do not believe that any blanket provision can be made such as is given here which will give protection, that this is presumed to give, to the allergic individual. The great proportion of those who are sensitive to foods do not know the exact identitiy of the food which is offensive. Furthermore, the matter of traces of those individual components of foods often becomes of great importance. There is also the matter of tolerance to be considered. I would illustrate that merely by one example of a baker's product in which the oil or fat used on the tins becomes as much an ingredient of the product, for the allergic, as the shortening or the yeast or the flour.

Not long ago an allergist called—and I wish to explain that I occupy a fellowship in the Department of Agriculture, provided by the cotton-seed industry, but I am not representing the cotton-seed industry or any other individual or manufacturer—and he wished to know whether there was possibly a fluid milk available in Washington from cows that had not been fed cotton-seed meal. He was recognizing the fact that milk may contain the allergenic ingredients of the feed of the cow. Any logical extension or interpretation of an effective labeling procedure for the protection of the health of the allergic individual must go far beyond the statement of the common names of the components.

Senator COPELAND. You would not want it to include the statement that the cow would not get cotton seed?

Mr. STEVENS. It would be necessary for the protection of that particular individual to label milk with the ingredients as to the cow's diet, which is obviously impractical.

Senator COPELAND. I just heard that the House had cut down the appropriation for the Agriculture Department. They would have to have a lot more money, wouldn't they, to do all of that?

Mr. STEVENS. They certainly would.

I would suggest that in the case of labeling foods that the provision be made, as it is not now made, so that the public health and food standards committee might determine those products which should be labeled. In that section about describing the food standards committee this paragraph seems to have been omitted from consideration.

Senator COPELAND. Your objection to page 8, subparagraph (i) relates to the exemption of spices, flavors, and colorings?

Mr. STEVENS. I submit that as an illustration. My suggestion is, and with your permission I shall file a memorandum on it, that the provisions be made for specifying on the labels of all foods, drugs, and cosmetics, the name and quantity of any one and/or all ingredients when there is involved a question of significant hazard to the health of the individual consumer as determined by the judgment of the Public Health and Food Standards Committee. Inhalants are more important than foods in the total number of allergic individuals.

I believe from my own experience that this subject of allergy is extremely important to the health of a certain number of individuals that are presumeed to be now unprotected, but I believe we are not now in a position to say exactly what items of any food or drug or cosmetic should be named on the label.

I have given this subject a great deal of study. I do not see how we would have been better off had we been able to read on the label the ingredients unless that label stated infinitesimal traces. Obviously that is not practical. The quantity of substance that sometimes does very grave damage is beyond chemical determination, and your allergic individual is the only test animal that you have.

I respectfully make the suggestion that consideration be given to this matter. I have referred to a few names of allergists; I am not an authority on it myself. I have not been able to stimulate enough interest in them to volunteer their opinions. One allergist here in town tells me it is not possible, in his view, to obtain protection, for the allergic individual, that many believe is possible by a statement of the composition.

Senator COPELAND. I have forgotten his name, but I think that doctor testified last year.

Mr. STEVENS. No. It was another one.

Senator COPELAND. It was another one? We had very full testimony I remember from some authority.

Mr. STEVENS. And I would like to ask for my own information with respect to those standard foods. Is it contemplated that a food that has a standard of quality where it is a mixed food such as a salad dressing, would that bear on the label the identity of every ingredient?

Senator COPELAND. I suppose no standard of quality would be fixed.

Mr. STEVENS. You see there is a reasonable chance for the use of several optional ingredients, the fats or oils in a food for instance, those may be capable of producing an allergy, although there is no effective means of controlling that from the Federal standpoint because of the difficulty involved in identifying those fats and oils.

Senator COPELAND. Of course, this bill as it is written permits a definition and standard of identity, and so forth. And then if it varies from that, the ingredients would have to be named.

Mr. STEVENS. They would have to be named?

Senator COPELAND. Of course, when you get into the subject of allergy, you know from your own experience how extremely difficult it is to deal with it.

Mr. STEVENS. I believe that is right, that is the reason I feel this provision on labeling should be extended to foods and drugs and cosmetics. But let us use the expert opinion that is available in these public health and food committees and determine on the basis of their judgment when and to what degree of——

Senator COPELAND. Would your doctor be willing to prepare for you a statement which you might send forward for the record?

Mr. STEVENS. I asked him if he would testify. That is H. S. Bernton. I have also talked to Dr. Warren T. Vaughn, of Richmond, whom you no doubt know.

Senator COPELAND. I think, Mr. Chairman, we would be glad, if it was promptly sent forward, to include that testimony as part of the testimony of this witness.

Senator GIBSON. Is it to be submitted in the form of a statement?

Senator COPELAND. Yes.

Mr. STEVENS. I would like to submit this brief in connection with my testimony.

(The brief referred to is as follows:)

There are presented in this memorandum some facts believed to be pertinent to the formulation of labeling provisions for foods wherein the purpose is to provide protection for those hypersensitive or allergic individuals whose health is impaired by eating foods of a character considered wholesome for the normal or nonallergic individual.

Reference is made to S. 5 Committee Print 31, section 302, paragraph (i), on page 8, subdivision (2). This paragraph has been represented as providing protection for that portion of the allergic population whose health may be endangered by consuming foods of unknown composition. It is my belief that the provisions of subdivision (2) of this paragraph (i) cannot be reconciled with certain established scientific principles relating to the cause, occurrence, and prevention of those disease entities due to individual and specific hypersensitiveness to common ingredients of foods usually regarded as wholesome in the amounts usually consumed. This group of diseases is called allergic diseases and the substances causing them are referred to as allergens or allergenic substances.

The facts and views here presented are intended to supplement the testimony recorded in the hearings on S. 2800 with respect to allergy and with respect to the benefits expected to accrue to the allergic individual through the statement of composition on the label of mixed foods. The information presented, I believe, faithfully represents the results of a thorough, unbiased, and competent evaluation of the major portion of published and otherwise available evidence concerning food allergy.

1. The exception provided in subdivision (2) of paragraph (i) "except that spices, flavors, and colorings, other than those sold as such, may be designated as spices, flavors, and colorings without naming each" fails to recognize that these are capable of inducing disease reactions in some allergic persons.

The fact that normally wholesome, nutritious foods may be for some individuals poisons of high potency is not a recent discovery. However, the systematic study of allergic reactions to foods, in progress only since 1910, has established beyond doubt that nearly every food, with the possible exception of highly purified carbohydrates, is capable of causing allergic disease in some group of the allergic population. A review of the clinical evidence which has led to the recognition of an ever-increasing number of foods known to be contributory factors in allergic disturbances will show that there is not a sound basis for the exception noted.

This exception, applicable only to spices, flavors, and colorings, in effect classifies these food ingredients as being ever innocent of offense against allergic individuals. There is in the medical literature adequate evidence to prove that certain spices and certain essential oils used as flavorings are not infrequently, or, according to some, are rarely, capable of producing allergic symptoms in the same manner and by the same routes of absorption as are

those foods considered more significant from the standpoint of nutritive value and bulk. One case of a specific hypersensitive disease reaction to a harmless certified analine food color was reported last July in the Journal of the American Medical Association. Consideration of the number and variety of substances used and properly designated as spices and flavors must, I believe, permit this conclusion: That the declaration of cinnamon as "spice" or oil of lemon as "flavor" will not be more effective in protecting the health of one portion of the allergic population than would be the declaration of wheat as "cereal" or egg albumin as "protein" for another group of the same population. Such a discriminating distribution of the benefits of paragraph (i) cannot be justified by the fact that the wheat-sensitive and egg-sensitive individuals surpass in number those who are sensitive to cinnamon or to the oil of lemon. Viewing the rate at which newly discovered allergens have been reported in the past few years does not justify the conclusion that a food ingredient is not capable of causing allergic disease if it has not yet been so identified.

As a member of the allergic population I favor most heartily the enactment of any enforceable labeling provision which can promise equitable benefit to the very small proportion of allergic consumers who are now or ever will be able to recognize by common name the particular ingredients of mixed foods causing their particular form of allergic disease.

2. A quantitative statement of composition of mixed foods is as significant to the allergic consumer as is a statement of identity of the ingredients.

Each allergic individual manifests some degree of tolerance toward the allergens which are for him specifically disturbing. This tolerance is sometimes so high that only excessive indulgence in a particular food provokes disease reactions. The tolerance may be so low that serious symptoms result from the ingestion of minute quantities of an offending food. Fortunately, this latter type of food allergy is rare, but, owing to the bizarre reactions sometimes observed in this type of allergic manifestations, their significance may be subject to overemphasis. The fact is not to be ignored, however, that in some instances an infinitesimally small quantity of a specifically disturbing substance can produce incapacitating disease, or profound shock, or even death. Such manifestations of allergic disease from ingestion of both foods and drugs warrant serious consideration even though not representative of the usual allergic reactions.

There is no rule or diagnostic method, other than that of personal experience, by which can be determined the tolerance of an allergic individual toward a particular allergen. On the basis of present knowledge the conclusion seems justified that a significantly useful statement of ingredients of a food will recognize those components present in traces as well as those present in large proportions. Also in view of the matter of tolerance it would appear that the declaration of an ingredient, unaccompanied by a statement of quantity would be quite as deceptive and misleading to the allergic individual, possessing a considerable degree of tolerance, as no statement at all.

Illustrative of some of the complexities encountered in labeling foods in such manner as to protect the health of all or a major proportion of the allergic population are these examples. The fat used on the baker's pans, being absorbed by the crust of the baked product, becomes an ingredient of importance to the individual sensitive to traces of that fat. That example is taken from a known clinical case of exquisite sensitiveness to a particular type of fat. The small quantity, of no significant nutritive value, of egg albumen used as a glaze on some baked goods is to the egg-sensitive consumer more important than the flour, yeast, and salt components. The identity and quantity of each ingredient would be significant to some group of allergic consumers.

A pure fat or a pure carbohydrate is not by current conceptions conceivably capable of producing allergic disease. However, both fats and carbohydrates widely used in foods are classified according to their source and are considered as allergens insofar as they carry traces of the proteins or allergens characteristic of the plant of animal tissue from which they are derived. Butter contains small but significant quantities of milk protein and this fat is often disturbing to the milk-sensitive subject. In some known cases of hypersensitiveness to the allergens of cottonseed, peanut, and corn or soybean the usually acceptable designation "vegetable oil" is wholly inadequate. To demand identification of these oils, or fats made from them, would imply that they were

distinguishable by analytical means suitable to the control official. Actually, the refined and hydrogenated vegetable oils are practically indistinguishable, particularly when mixed.

Honey is frequently used as a sweetening and flavoring ingredient. Obviously, there is no advantage to the normal individual in identification of honey employed in this use with respect to the blossoms from which its sugar was derived. However, decidedly important to the allergic individual possessed of a pollen sensitiveness is the information which would declare to him whether the particular variety of honey employed was for his use a food or a poison.

In conclusion I submit that paragraph (i) of section 302, as it now appears in the committee print no. 31, is not capable of furnishing protection of significant value to either allergic or normal nonallergic consumers. Therefore I suggest that provision be made for specifying on the labels of all foods (and drugs and cosmetics as well) the name and quantity of any one or all ingredients when there is involved a question of deception or fraud or a significant hazard to the health of consumers, as determined by the judgment of the public health and food-standard committees.

For the information of the committee I am suggesting the following as consultants in matters concerning allergy: Dr. H. S. Bernton, Washington, D. C.; Dr. R. A. Kern, University Hospital, Philadelphia; Dr. Warren T. Vaughan, Richmond, Va.

Mr. STEVENS. Dr. Bernton would be glad to testify when you have time to hear him.

Senator COPELAND. We do not have time for any new witnesses, but if you will incorporate in your testimony those statements and send them forward promptly they will be included in the record.

(Statement referred to is as follows:)

MEMORANDUM TO THE COMMITTEE ON COMMERCE

I am acknowledging and complying with the request of Senator Royal S. Copeland, extended to me through your witness, Dr. Henry Stevens, to submit to the Committee on Commerce this statement of my views concerning certain provisions of S. 5. My testimony is with reference to section 302, paragraphs (g) and (i), as they appear in committee print no. 31.

If I have interpreted correctly relevant portions of the testimony recorded in the hearings on S. 2800, the chief intent of the proposed legislation on the labeling of foods is to eliminate through prescribed label declaration the hazards presumed to be inherent in the purchase and consumption by the allergic patient of those foods to which he reacts unfavorably.

My commendation is at once due those who have been responsible for this sincere attempt to so regulate the practices of food merchandising that the allergic consumer might be enabled to read the labels and distinguish the safe from the dangerous in his selection of an enjoyable and healthful dietary. I regret that I cannot support the view that a declaration of the common names of the ingredients of certain foods, for which a definition and standard of identity is not prescribed, would confer significant benefit to those allergic individuals who find foods an important cause of their abnormal reactions. Unfortunately, the practice of preventive measures in the management of allergic diseases has not become simplified to a degree implied by this plan. In fact, I find in my experience a basis for believing that the allergic patient would in some instances regard with undue apprehension the declaration of an ingredient to which he manifests a positive, but not a clinically significant, skin reaction. The skin test is of recognized value in delineating the causative factors in some allergic diseases but experienced allergists concede that the skin may be more sensitive or less sensitive (or even entirely refractory) than those structures which manifest the outspoken symptoms of allergy. Often, particularly difficult is the identification of the specific dietary ingredients which the allergic patient should avoid. When once identified, either through skin test, experience, or history, there are not infrequently unexplainable vagaries in the degree of sensitiveness of the patient to the same food in different forms, under different circumstances. The egg-sensitive patient, for example, may react clinically only to egg eaten as such, while the egg component of cake is wholly innocuous. Avoidance of all egg-labeled foods by this type of allergic patient

would mean unwarranted deprivation of pleasures to which he might be entitled by some degree of ignorance.

To contemplate the regulations necessary for protection of the unusual patient who manifests a violent reaction to a trace of some disturbing food ingredient would be a monumental task indeed, but one not feasibly ignored if the intent of the law were protection of the health of the individual allergic consumer. In that circumstance no single item, whether protein, fat, flavor, or spice, whether ingredient or merely an adjunct to the technology of food production, could bear exemption from declaration. The allergic subject so protected might expectantly scrutinize the label not only for the common names of the ingredients of a food but also for the statement of quantity, the history, and mode of preparation. Identification of the meat of fowl, in illustration, would need to qualify not alone by the common name of "chicken meat", but also by history of its origin, whether from the hen or rooster. There yet exists no effective means by which the offending item of the dietary can be certainly recognized other than by the sometimes unfortunate consequence of a warning experience. There has not yet been devised analytical means of such precision as to demonstrate either qualitatively or quantitatively those substances which at some time become significant to the potentially allergic. It is a fact also that most food allergic individuals are among that portion of the population which does not find necessary the counsel of the allergist in order to lead a normally comfortable life. These individuals learn by observation those items or combinations which must be altogether excluded from their diets and those which may be enjoyed if taken in measured moderation.

It is my opinion that commensurate benefit to the allergic population would not be likely to result from declaration alone of the common names of food ingredients, either with or without a quantitative statement; for this purpose, necessarily barring exemptions for the privilege of optional selection of ingredients in foods of a defined standard, and bearing also exemptions on the basis of impracticability or proprietary rights to secret formulas or process of preparation.

My views are based on experience gained through 12 years devoted exclusively to clinical study and treatment of allergic patients. In this interval I have had the privilege of serving as president of the American Association for the Study of Allergy, and have contributed to the medical literature the results of individual investigations and research programs, instituted through my own efforts but executed in collaboration with distinguished scientists of the United States Department of Agriculture.

This testimony is submitted in my own behalf and without compensation.

HARRY S. BERNTON.

Mr. STEVENS. Thank you, sir.

Senator GIBSON. Mr. Peterson?

(No response.)

Senator GIBSON. Mr. Funk?

STATEMENT OF ERWIN FUNK, MEMBER LEGISLATIVE COMMITTEE ON NATIONAL EDITORIAL ASSOCIATION, IN SUPPORT OF COPELAND FOOD AND DRUG ACT

Mr. FUNK. My name is Erwin Funk, of Rogers, Ark. I am a member of the legislative committee of the National Editorial Association and a past president of the association. I am directly representing the 5,000 members of the association, and indirectly the 10,000 small-town weekly and daily newspapers with which we are affiliated through the various State press associations of the country.

Our legislative committees have for a number of years scrutinized very carefully all bills involving food and drug regulations, which may directly or indirectly affect local and national advertising.

Our legislative committee has watched S. 5 from its introduction and followed carefully all changes and amendments, made or suggested. As the bill stands today it has the unqualified endorsement of the National Editorial Association as being fair in its treatment of the publishers in all sections affecting their interests.

Last Saturday I heard with interest the changes in wording suggested for section 601 (a), page 2, line 4, which would substitute "supported" for "sustained." This by Mr. Benson of the American Association of Advertising Agencies. Also the suggestion by Mr. Dunn that the words "and recognized" be inserted in line 5 of page 24, between "substantial" and "medical." Both or either of these changes will be acceptable to our members.

I think the record of the small-town weekly and dailies substantiates my assertion that as a whole they have ever placed the interests of their communities ahead of their own, and they are perfectly willing to trust the committee of the Senate as to the proper wording of S. 5 to protect the best interests of their readers and their families. We are accepting the statement that S. 5 is a bill to protect public health, and are opposing proposed amendments that would carry it into other fields.

Therefore, we reserve the right to withdraw our support of S. 5 if amendments be adopted which we believe change the intent of the present bill, or that materially affect our interests as publishers.

The National Editorial Association has little or no fault to find with S. 580, introduced by Senator McCarran, and H. R. 3972, introduced by Congressman Mead, insofar as they affect our publishers. However, in view of the fact that our legislative committee is more familiar with the provisions of S. 5 and has given it their endorsement in its present form, I am urging the adoption of S. 5.

Senator GIBSON. Dr. McClendon? (No response.)

Senator GIBSON. Dr. Hilton? (No response.)

Senator GIBSON. Dr. Harrisson?

STATEMENT OF DR. JOSEPH W. E. HARRISSON, OF LA WALL & HARRISSON, CHEMISTS, PHILADELPHIA

Dr. HARRISSON. I first want to express my appreciation for the attention which the prior committees have given to me individually, and also the others appearing at that hearing, and also the great attention and consideration that was given to us at this hearing.

I want to state first that I am appearing as an individual. My name is Joseph W. E. Harrisson, residence in Philadelphia. I appear as an individual primarily because I feel that over a period of over 15 years I have been actively interested in public welfare as represented by the control of food and drug products. During that period of time, I have been associated with Dr. Charles H. LaWall, who is well known in regard to his stand for strict enforcement of food and drug acts, and during that period of time, we have ourselves probably examined well over 100,000 samples of foods and drugs in relation to their purity and standards and commented in many cases upon their label requirements and the statements contained on those labels.

I do not appear as a representative of any pharmaceutical manufacturing concern, any food industry, or any advertising concern, and I do not say this disparagingly, for I have the fullest confidence in most of these concerns and individuals.

We as individuals, and I speak for both Dr. LaWall and myself, recommend and feel that the prompt reporting out of S. 5 with a favorable recommendation to the general committee is desirable. However, I would like to take up several specific points in the bill, which I feel should be modified in the interests of clarity in the bill.

I refer first to chapter II, section 201, which contains the definitions, and particularly under section (c) which states the definition of cosmetics. We note the exclusion at that point of the term "and devices", which appears in the previous definition for drug products. I would suggest the inclusion at that point of the term "and devices", for, as we all know, there are many devices which are used for cosmetic purposes which should be under the control of such an act.

Senator COPELAND. Yesterday Miss Wall made the same suggestion, that after "preparations" on line 17, should be the insertion of "and devices." That is your suggestion, too?

Dr. HARRISSON. I am fully in accord with that, Senator Copeland. We recognize the fact that years back practically all medication was introduced through the oral tract to a large extent, Then came those pieces of apparatus for application to the body directly or indirectly, and now today we find medication being introduced through the use of such substances as chewing gums to reduce weight or act as laxatives, which normally years back were more or less confections, and now strictly enter into the field of medical products.

Senator COPELAND. I saw some cigarettes yesterday which——

Dr. HARRISSON (interrupting). I have a package of the cigarettes with me [producing]. We can now get thin by smoking. We can take off 4 pounds a week by merely smoking cigarettes.

Senator COPELAND. Have you an extra package?

Dr. HARRISSON. I have one here. It contains a thyroid extract in the cork tip. As you suck it, proportionately to the degree that you smoke it, you can take off relatively, according to their claims, 1 to 4 pounds a week.

Senator COPELAND. Then you should not use a holder?

Dr. HARRISSON. No; it probably will not work if you use a holder, yet they do not state on the directions the means that should be used.

Senator COPELAND. If the cigarette fails, it is because the user smoked with a holder. [Laughter.]

Dr. HARRISSON. I would presume that to be so. At least, that would be a reasonable explanation by the seller or purveyor of the product. It is ostensibly for use by the medical profession, as you will note, but generally it reverts to public use, as we all know, and likewise becomes a general menace to the health of those who do not realize the extent to which they become habitues of a fallacy or fallacious act.

Senator COPELAND. They would use this without knowledge that they were taking a drug that might do serious harm?

Dr. HARRISSON. Thyroid extract is undoubtedly one of the most potent drugs that we have to deal with.

Senator COPELAND. I will leave those with you, Senator Gibson.

Dr. HARRISSON. I doubt if your associate requires it.

Senator COPELAND. I think it is a very interesting exhibit.

Dr. HARRISSON. Referring to section (k) in which a definition is given for the medical profession or medical opinion, I would earnestly request that the committee broaden this definition so as to include other related sciences. I think it will be admitted by physicians and practitioners in medicine that other related sciences are just as important in establishing medical opinion. In most instances, or rather in many instances, important medical discoveries arise from pharmaceutical chemists and others, and because of that fact, consideration should be given to other sciences than medical science.

I refer to a statement of yours this morning in which you presented a clipping relative to a condition in Chicago. That diagnosis was probably made by a physician. It has already been broadcast through the newspapers. But you will note that in the newspaper statement the product is being sent to the laboratory for examination. In 90 percent of similar cases, after subsequent examination, the diagnosis is changed, and that is based not upon medical opinion, and not upon the action of any physician himself, but upon the action of those practicing in a related science.

As a modification of that section, I will submit a prepared suggestion: In chapter II, section 201 (L), add: "as well as the opinion of those practicing in the sciences related to medicine."

Referring to chapter III, section 301, part (h), I would earnestly request that an additional section be added, to be known as "section 5", and I will, with your permission, speak briefly upon this.

I propose that you add an additional section, which reads:

(5) Or if by any means it is made to appear better or of greater value than it is.

I believe that fully covers the reference you made this morning to the use of oranges artificially colored and probably concealing not damage, or probably concealing not inferiority when they are compared with oranges produced from the same section, but certainly making them appear to be of greater or better value than they actually are.

Going further, to section (d), I am referring particularly to the section now as it stands excluding the uses of resinous glazes on confectionery.

I am in favor of retaining the present section as it now stands, excluding the use of resinous glazes. This lac which has been referred to here before this committee is in effect the use of shellac, and in a large majority of cases those individuals marketing confections and using such products, use the same material that is used for the covering of floors. It is true that today it does not carry in it the gross adulteration that it did 25 years ago. We do not see to any great extent the presence of arsenic with which it was so grossly adulterated some period of time back. However, I believe it constitutes what is practically an embalming of the confection. It makes for its lasting retention on the shelves of the individual for an unlimited period of time and should be avoided.

Other products which will give the similar effect insofar as preventing the candy from sticking or as to giving to it a shining appearance, if desirable, are available and are used by many and some of the largest manufacturers.

Senator COPELAND. I wish you would enlarge a little upon this subject, if you will. It is an important one. You heard the testimony this morning of Mr. Hoops. Is it your feeling that it is a harmful thing to use?

Dr. HARRISSON. I would not say that, properly purified, it would not be necessarily harmful. I would say that in a large measure the quality of the material that is used is not satisfactory.

Senator COPELAND. That is to say, if you will pardon me, if it were prepared as the chemist with Mr. Hoops suggested, and properly purified, that would not be harmful, but the difficulty is to differentiate between such a harmless product and one which might be really a modified varnish.

Dr. HARRISSON. Yes; that is a difficulty. In addition, I particularly object to the use of a product which will maintain a product such as a candy, which is ostensibly a food product, on the shelves of the purveyor for an unlimited space of time.

Senator COPELAND. Is that because there might be bacterial contamination or growth within the candy by deterioration?

Dr. HARRISSON. A change within the candy structure itself, and as a rule or in many cases I would rather say, the use of such lac or shellac or surface coating is used principally where the chocolate coating on a candy is put on with what I might say was microscopic neatness.

Senator COPELAND. An infinitesimal quantity.

Dr. HARRISSON. Yes.

Senator COPELAND. That is, it gives an opportunity to lead to gross deception in that the glaze would be in place of and give the appearance of a lot of chocolate, but it is not there.

Dr. HARRISSON. Sincerely I believe that is so; yes, sir.

Senator COPELAND. That is, its use in there has the possibility at least that it would lead to gross deception of the consumer.

Dr. HARRISSON. I believe it makes the product appear of better value than it is.

In the same section, under the division L, referring to the transportation in interstate commerce of natural food products without a label attached thereto, or of the transportation in interstate commerce of processed food products without a label attached thereto—referring particularly to canned goods probably—you probably recognize that there is a transportation in interstate commerce to a large extent of canned goods, such as canned peas, fish, tuna, salmon, and vegetables, to which is attached no label on the individual package which will eventually reach the customer. If this section will control the subsequent labeling of these goods after they have passed the State boundary line, I would see no objection to it, but the practice in many instances is to receive through interstate commerce goods which are of a lower quality than what they are later branded with within the State boundaries.

Pink salmon is received unlabeled. It comes out of the processing or relabeling plant as red salmon. Soaked dried peas come through unlabeled and come out as June peas. That places a responsibility directly upon the individual States in the enforcement of your act regulating such products, but I believe that under this section, as drawn, it is the intent of the committee to only permit this transportation under such conditions where the establishments agree to label

the subsequent products in conformity with the act had they been labeled when they were in interstate commerce.

Senator COPELAND. It provides that shall be done by regulation.

Dr. HARRISSON. I notice it does. I would suggest, however, an additional section which would clarify that, and this suggestion is to add to section 302 (L) a second section as follows:

(2) Subsequent to such labeling, relabeling, reprocessing, or repacking any movement, sale, or offering for sale shall be construed as a continuation of the interstate traffic in the original product.

This same applies to other sections. I believe sections 402 (L) and 502 (d), which refer to drugs and cosmetics.

Senator COPELAND. Let me get those references, please.

Dr. HARRISSON. 402 (L), which is identical in the case of drugs, and 502 (d).

Senator COPELAND. Thank you.

Dr. HARRISSON. In reference to section 303, there has been a request for the elimination of any control or the promulgation of standards affecting dried fruits and vegetables.

Senator COPELAND. What have you to say about that?

Dr. HARRISSON. I have this to say, sir, that it is the intent under this act to promulgate standards for canned foods and vegetables. There is also not only an intent but an actual act now controlling the quality of fresh fruits and vegetables under the Bureau of Agricultural Economics. If this request is granted for eliminating the control of dried fruits and vegetables from this act, they will then remain the only food product over which there is no control insofar as their standards of quality are concerned.

Senator COPELAND. I wish you would make that clear. Fresh fruits and vegetables are now regulated——

Dr. HARRISSON. By the Bureau of Agricultural Economics.

Senator COPELAND. So they might be exempt and still the public is protected.

Dr. HARRISSON. Under standards enforced by the Bureau of Agricultural Economics.

Senator COPELAND. But if we were to exempt dried fruits, there would be no control.

Dr. HARRISSON. It would leave them with no control under any act. Certainly the public can well observe the quality of fresh fruits when they purchase them, or fresh vegetables. Certainly they cannot observe the quality of canned foods when they purchase them, for the can conceals what may be within the can, and likewise they have not the ability to observe the quality of dried fruits or dried vegetables.

Furthermore, there is no reference made to the large use in those products of preservatives, such as sulphur dioxide, which is present in many cases in relatively large quantities.

Referring to section 305, emergency permit control of factories, we are heartily in accord with this section. We presume it is meant specifically to apply to plants packing fresh fish products or fresh shellfish, such as crab or lobster or similar products.

Senator COPELAND. I would like to ask you this if I may. It has been suggested that this trouble is largely local trouble, that is, there are certain geographical localities, where this evil occurs. Would

there be any objection to including on line 17 thereof "in any locality" or "any given locality", or something like that?

Dr. HARRISSON. I do not think it requires that inclusion, Senator.

Senator COPELAND. You do not think so?

Dr. HARRISSON. No; I do not. I would say that the wording of the section as drawn seems adequate. There is only one thing I have in mind. Reading that section in connection with section 708, subdivision 8, page 35, I am apprehensive of what the department might do. I am particularly apprehensive of the fact that they may include such products as canned shrimp, and I am referring to fresh shrimp and not processed shrimp, or canned lobster or canned crab meat, with a stamp or statement indicating that the product has been inspected and passed, or that the plant has been inspected and approved by the Department, much as is now done under the Meat Act, where such stamp appears upon a side of meat reaching the ultimate purveyor to the consumer.

I see great possibilities of raising in the consumer an unwarranted faith in the product which he is buying, if such is the case. We all know that fish or shrimp or any similar product if inspected at the point of take or at the point of shipment, may be in a sound condition, but 24 hours thereafter it may be in an absolutely unfit condition for consumption by the normal human individual, and if under such circumstances the package carries an inspection stamp or approval stamp, I see the possibility of lulling the public or consumer into the thought that he is necessarily getting a product safe and suitable for his consumption. I would say that there should be some provision made whereby no such inspection stamp appear to give any approval to the product as it reaches the consumer.

Senator COPELAND. Have you suggested language?

Dr. HARRISSON. I have submitted no special language upon that.

Senator COPELAND. Will you do so?

Dr. HARRISSON. I will be glad to do so.

Senator COPELAND. I should like to ask you also: An amendment has been offered in the Senate to amend this bill by changing under "misbranded food" where it says "the name and place of business of the manufacturer, seller, or distributor", lines 16 and 17, page 6, that there should be inserted "and if canned salmon, the geographical name of the river, stream, bay, or sound, or general geographical name of the locality in which the salmon were caught."

Dr. HARRISSON. I would be most heartily in favor of that.

Senator COPELAND. Why would you be?

Dr. HARRISSON. Because I believe that to many purchasers, the locality in which the salmon is caught indicates a superior product. In other words, Alaska salmon indicates a far-superior salmon to a salmon which is caught in southern waters.

Senator COPELAND. Would it mean anything to the general public?

Dr. HARRISSON. I believe it would. If the present marking upon the cans, in most instances of such products as are caught in Alaska is indicated as the geographical location, as in many instances Alaska salmon is now marked, it must mean something to the purveyor of that product, or he would not so mark the product. Therefore, it must mean something to the consumer.

Senator COPELAND. So you would approve it?

Dr. HARRISSON. I certainly would.

Referring now to chapter 4, section 401, part 5—that is in subdivision 5—this has already been mentioned before your committee, in which it has been brought to your attention that coal-tar colors or similar products are therapeutic agents in many cases. I have in mind methylene blue, acriflavine, scarlet red, mercurochrome, and many others. Under the section as now drawn, it would require the approval by the Department of Agriculture of every batch of such products which were made before they might be used in medicinal products. I would suggest, and probably it is not the intent in this case to control only those colors which are used for coloring purposes——

Senator COPELAND (interrupting). A very distinguished citizen yesterday advocated the inclusion on line 16 after the word "contains" of the language "for the purposes of coloring." Is that what you are proposing?

Dr. HARRISSON. Practically so; but I believe it should be more explicit than that statement.

Senator COPELAND. What would you say?

Dr. HARRISSON. I would add after the general statement in that section "except when not used for coloring and present in quantities having a therapeutic value."

Senator COPELAND. "Except when not used for coloring and present in quantities?"

Dr. HARRISSON. Yes. "And present in quantities having a therapeutic value." It might reasonably be conceived——

Senator COPELAND (interrupting). What was that last?

Dr. HARRISSON. "And present in quantities having a therapeutic value."

Senator COPELAND. You mean therapeutic effect?

Dr. HARRISSON. Effect; yes; or value. It might be reasonably conceived that such products that I have already mentioned might be used for coloring purposes.

Senator COPELAND. Might be used for what?

Dr. HARRISSON. Might be used for coloring purposes alone, and the excuse given that they were used as therapeutic agents.

Senator COPELAND. If some homeopath were on the stand he might say no matter how minute and infinitesimal the amount, it might have some effect.

Dr. HARRISSON. I believe they might, with all due respect to the homeopaths.

Senator COPELAND. Now, suppose we say "and present in quantities having a physiological effect."

Dr. HARRISSON. That is rather a broad statement, but I would be willing to change to such a statement, Senator.

Senator COPELAND. Now, just why are you proposing this? I want to support the contention of this distinguished gentleman who appeared yesterday.

Dr. HARRISSON. In the case of certain of these products, methylene blue, for instance, its character and purity is now controlled by the United States Pharmacopœia. There is a standard in this compen-

dium for the quality and purity of methylene blue. In the case of certain other medicinal products, while not controlled by official compendiums, they are at least referred to by unofficial ones. Furthermore, in the case of certain proprietary products, such mercurochrome, their quality is controlled by the manufacturer. If the Department desires to enter into the examination of such products as may be of a coal-tar origin and have a tinctorial value and establish the standards of quality and identity for all such products which may use as remedial agents, then I see no objection to the sentence or phrase as it now stands. However, I feel that that is not the intent of this section, in consequence of which they will merely control coloring agents, and then if such products as we have in mind, such as methylene blue, are added to pharmaceuticals, for the purposes of deceit there will be no basis upon which the Department might proceed against such products. They would probably be there in amounts not producing a satisfactory therapeutic effect, but yet the user would have a just defense in the claim that they do not come under those products used for coloring purposes alone.

Senator COPELAND. Is back of this the though that these coal-tar colors might be harmful to health?

Dr. HARRISSON. I think there is back of this original phrase the thought that coal-tar colors might be harmful to health.

Senator COPELAND. Might some of them be harmful to use for coloring purposes?

Dr. HARRISSON. Some of them might be harmful, yes, particularly by the inclusion of either components not specifically those which should be there, or by the inclusion of such products which are arsenical, which are often used in the manufacture of such products.

Senator COPELAND. Don't you think it might be better if you are going to change the section 5 or paragraph 5, perhaps to leave the determination a little bit to the regulation? It is limited now if it contains a coal-tar color other than one from a batch that has been certified. Why could it not be worded something like this: "If it contains"—do you see what I mean?

Dr. HARRISSON. Yes.

Senator COPELAND. To give latitude to the regulatory body to exclude from the operation of the law those substances which they consider to be harmless. Would that cover the thought you have in mind?

Dr. HARRISSON. I wonder if it actually would, Senator. In many cases products used as therapeutic agents to some individuals are harmful, and if tested by a pharmacological means that harmful state can be demonstrated, yet they are recognized therapeutic agents used in medicine for either the prevention or cure of a disease.

Senator COPELAND. I catch the thought you have in mind. I was just wondering if we are not a bit confused as how we should deal with it. Your thought is, we should add at the end of that line 18, "except when not used for coloring, or is present in a quantity having a therapeutic effect or a physiological effect, or a harmful effect, or something?"

Dr. HARRISSON. "And present in quantities having a therapeutic value."

Senator COPELAND. Does that meet your suggestion, Mr. Craig?

Mr. CRAIG. Senator, I do not consider that necessary really if you phrase it "if it contains a coal-tar color other than one from a batch that has been certified in accordance with the regulations as provided by section 403, 701, and 703." I think that takes care of it.

Senator COPELAND. You still think the language you suggested yesterday on line 16, if I understood you, is proper?

Mr. CRAIG. After the word "contains", "for purposes of coloration."

Senator COPELAND. For purposes of coloration?

Mr. CRAIG. It does not matter as to the wording. I think that would cover everything sought to be covered.

Senator COPELAND. Do you think so, Dr. Harrisson?

Mr. HARRISSON. I would be glad to think it would, but I am apprehensive of the possibility that it places upon the department the burden of proof that the product used is for coloring purposes.

Senator COPELAND. We have to bear in mind that this bill is for protection of the public, the consumer. Are we not all of the time open to criticism that we are permitting the addition of a coloring material which is really deceptive, which leads to deception, which leads to misleading the public?

Mr. HARRISSON. In pharmaceuticals, the use of such products for the purposes you have mentioned, are relatively rare, for I feel that the public in a large measure has no means of knowing whether a highly colored product or one which is not highly colored is of either better or greater value in the case of a pharmaceutical, and while I am in strict accord with the prevention of such deception by coloring, neither do I want to phrase the section in such wording that will make it necessary for the Department, if they feel that some product has been colored, we will say, by the use of methylene blue, which is a recognized medicinal agent, to establish in court that the purpose of the addition of that methylene blue was only for the purpose of coloring. I would rather see the section go on further to state if methylene blue or some similar product was used, then it must be there in sufficient quantity to have a therapeutic or physiological effect, which would remove it from the necessity of the Department proving that it was there for coloring purposes.

Senator COPELAND. That is a very interesting point. I can see the propriety of that if we can without being open as to the charge of being a party to deceiving the public, and I can see how something might be worked out. Anyhow, note has been made of your suggestion, Mr. Harrison.

Mr. HARRISSON. Thank you. I will now refer to section (*b*) or rather, section 401, paragraph (*b*), which we all know is the variation clause, and where angels fear to tread.

Senator COPELAND. You are a candidate for the medal, I see.

Mr. HARRISSON. I am only going to mention for your consideration, that a change be made in lines 14 and 15.

Senator COPELAND. Page 14?

Mr. HARRISSON. Page 14; "bears in juxtaposition with the name of the drug a statement to the effect not 'U. S. P. 10 formula' or 'not N. F. V. formula', or 'modified U. S. P. formula', or 'modified N. F. 5 formula'."

Senator COPELAND. I will tell you why about that. I realize that none of us can agree when we come to this, but if you put upon the article that it is not this, or not that, you raise a serious question in the mind of the intelligent consumer as to whether it is a good thing.

Mr. HARRISSON. That may be so, Mr. Senator, but do such products in their original containers reach the consumer? Is not this act insofar as this particular section is concerned largely for the protection of the pharmacist, who eventually dispenses such products to the consumer? And if in that instance it should bear upon the label " modified U. S. P. formula " followed by a statement as to, in what way it was modified, I feel the manufacturer would have a perfect liberty to adjust strength and probably color and flavor if he should so desire.

Senator COPELAND. Would there not be an implied, if not a direct, demand that if the pharmacist put up strength iodine that it should be so stated on the label?

Mr. HARRISSON. I believe it should be so stated.

Senator COPELAND. How many articles, as a matter of fact, of common use are involved in this question of variation?

Mr. HARRISSON. I would say there were a considerable number by the pharmacist.

Senator COPELAND. A dozen?

Mr. HARRISSON. Well, many more than that.

Senator COPELAND. One hundred?

Mr. HARRISSON. It is difficult to give definite numbers, but I would say yes; more than 100, even. They may not all come within the purview of the Pharmacopœia itself, you understand. And I think you should not forget it applies to those products in commercial use. We have such products as acacia and the various acids which, while official in the Pharmacopœia, are also used to a far greater extent for commercial purposes.

Senator COPELAND. So far as I am concerned, I throw up my hands on this matter of variation. Frankly, I do not know how it should be done.

Mr. HARRISSON. I think probably you and the committee can take the advice of those who are well available to give it.

Senator COPELAND. We have got plenty of advice.

Mr. HARRISSON. After the hearings and after you are out of the mess perhaps you can get something concrete.

Senator COPELAND. While you are on a controversial subject, are you an authority on antiseptics?

Mr. HARRISSON. I would not say an authority. I have some knowledge of them.

Senator COPELAND. Are you going to say anything on them?

Mr. HARRISSON. I expect to make one reference to them.

Senator COPELAND. All right.

Mr. HARRISSON. Going further to paragraph (d) of the same section, line 13, page 16, I would request the deletion of the word " chemically."

Senator COPELAND. Wait a minute. Where is this?

Mr. HARRISSON. Page 16, line 13.

Senator COPELAND. Yes; I see.

Mr. HARRISSON. I request the deletion of the word " chemically " and introduce, following the word " derived ", a phrase " by any means." It is true that most products would be chemically derived, but there is always a possibility of other means being developed.

Senator COPELAND. That is, you add " by any means." Where would you put that?

Mr. HARRISSON. I would make the sentence 13 then read:

hypnotic substance derived by any means therefrom.

Referring to paragraphs (j) and (k), or the paragraphs referring to the standardization of antiseptics or germicides, I have only one thought in mind.

Senator COPELAND. I am glad you have not more than one.

Mr. HARRISSON. And that is, I wonder if the Department has considered the effect upon the enforcement of the act of tying themselves to definite paragraphs as herein stated. I wonder if they would not have more latitude and more final enforcement value if these paragraphs were deleted and general enforcement left to the general provisions of the act. I have no suggestion as to substitute provisions. I do not directly suggest they be taken out, but I do feel that due consideration should be given to that thought.

Senator COPELAND. It is only because I hate to be accused of weakness that I have not long since told the Department that I thought they should be taken out, because these two subjects we have just referred to, variations, and the antiseptic provisions of the bill have been the most difficult. I suppose they seem particularly difficult to me because they are so highly technical. And I know it will be so when we get into the Senate, that most of us are hardly qualified to deal with those two problems. And so in the last analysis we will have to place dependence upon the advice that we get. I have recently had more substitute language presented, but there have been presented two paragraphs which, even though it bores the audience, I feel that the record should be quite complete on this subject, because we will have to defend the bill when it is finally written, and I am going to read this. And I notice Dr. Wright is here too, and I am glad, because I should like to have him hear it. I am going to ask whether or not this language for (j) would be an advantage. I do this, Doctor, while you are on the witness stand because you are competent to testify. Suppose we were to have (j) read:

(j) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the body and its labeling fails to bear plainly and conspicuously adequate directions for such use, and when used as directed it does not have the germicidal effect equivalent to phenol of a 1 to 80 aqueous dilution for 10 minutes at thirty-seven degrees centigrade: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of (1) failure of its labeling to bear adequate directions for any advertised use if such advertising is disseminated exclusive to members of the medical pharmaceutical professions; or (2) its failure to have the germicidal effect required by this paragraph if its own standard of such effect is stated on its label and such drug is distributed for use solely by the medical profession.

Is that worse than anything we have had before?

Dr. HARRISSON. I would hesitate to give snap judgment on that. I would like to have time to consider it. It certainly is probably more lenient than what we now have in the present draft of the act.

Senator COPELAND. And is it lenient to the extent of lessening protection to the public?

Dr. HARRISSON. I would want to give that consideration before answering it.

Senator COPELAND. Since the record is covering the matter for the moment, let me say that the suggestion that has been made to me about (k) is to have it read as follows:

If it purports to be or is represented as an inhibitory antiseptic for any use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body and its labeling fails to bear plainly and conspicuously adequate directions for such use, and when used as indicated, it fails to prevent the growth of microorganisms within the entire time of such use: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of failure of its labeling to bear adequate directions for any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical profession, or appear only in scientific publications of these professions.

I enter these for the record because some other time we have to study this matter again.

Dr. HARRISSON. I would be glad to submit an answer subsequent after I have an opportunity to study it, Dr. Copeland.

Senator COPELAND. Your recommendation was these paragraphs be stricken from the bill and the Department left free to deal with these medicinal agents the same way they do other drugs; is that right?

Dr. HARRISSON. No; I made no definite recommendations along that line. I recommended that the Department give due consideration to their hands being tied by specific sections in the bill. It would be rather difficult for them to go beyond that, if they would at any time find it desirable to do so. I do not recommend any substitute section, for I have myself been unable to prepare one which met fully with my own ideas.

Senator COPELAND. Then as a scientist you are just as bad off as I am, are you?

Dr. HARRISSON. To give full protection to the public and still a right and workable section I must confess I have lacked the ability to prepare it.

Senator COPELAND. You have lots of company.

Is it your judgment if we should delete those two paragraphs, is it your judgment from the study of the bill, that the Department would have ample power to deal with this germicide problem under the other features of this bill?

Dr. HARRISSON. I feel there would probably be some additional clause necessary to give them ample power.

Senator COPELAND. It is your feeling that there would have to be?

Dr. HARRISSON. Some additional clause.

Senator COPELAND. You feel there should be some additional clause?

Dr. HARRISSON. In the promotion of standards for medicinal products.

Senator COPELAND. That is, simply striking them from the bill without that additional clause would not be as ample protection as society needs?

Dr. HARRISSON. I do not believe it would be as full protection as they ought to have.

Senator COPELAND. Thank you.

Dr. HARRISSON. Finally, I refer to one subject which has been brought to your attention by a number of witnesses, and that is the transfer or, rather, the establishment of the advertising control features of the bill in the Federal Trade Commission. We sincerely feel that that would be a gross error, and that the Federal Trade Commission is constituted principally to do what its title says, control advertising insofar as it relates to competition, particularly among similar types of manufacturing or purveying to the public, and in the case of drugs, you and I know the decision in regard to one specific obesity compound in which there was no competition involved the Federal Trade Commission had no control of advertising of that product. I feel that the Department, and by the Department I mean the Food and Drug Administration, has the scientific backing and the ability to properly enforce and properly protect the consumers under the advertising section of the bill, and I heartily feel that any change causing this section to be under the control of the Federal Trade Commission would emasculate the bill.

A STATEMENT FILED WITH THE COMMITTEE ON COMMERCE OF THE UNITED STATES SENATE, IN REFERENCE TO PARAGRAPHS (J) AND (K) OF SECTION 402 OF S. 5 (COMMITTEE PRINT 3), PAGES 18, 19, AND 20. ON BEHALF OF THE NATIONAL ASSOCIATION OF INSECTICIDE AND DISINFECTANT MANUFACTURERS, INC., AND OF THE NATIONAL COMMITTEE OF MANUFACTURERS OF ANTISEPTICS

At the hearing before the Subcommittee of the Committee on Commerce of the United States Senate which took place on March 9, 1935, Senator Copeland read into the record a draft of paragraph (j) of section 402 submitted to him by the representative of the Food and Drug Administration, intended as a substitute for the wording of paragraph (j) as it appears in S. 5 (committee print 3).

The paragraph proposed by the Food and Drug Administration reads as follows:

SEC. 402. A drug shall be deemed to be misbranded—

(j) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the body and its labeling fails to bear plainly and conspicuously adequate directions for such use, and when used as directed it does not have the germicidal effect equivalent to phenol of a one to eighty aqueous dilution for ten minutes at thirty-seven degrees centigrade. *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of (1) failure of its labeling to bear adequate directions for any advertised use if such advertising is disseminated only to members of the medical and pharmaceutical professions, or appears only in scientific publications of those professions, or (2) its failure to have the germicidal effect required by this paragraph if its own standard of such effect is stated on its label and such drug is distributed for use solely by the medical profession.

To the first sentence of this proposed wording the same objections apply as have been made to the original wording of paragraph (j) by Prof. Samuel C. Prescott and Dr. George F. Reddish at the hearing before this subcommittee on March 8. To recapitulate briefly these objections, the proposed language is extremely indefinite in character, so indefinite indeed that it would not enable a trained bacteriologist to decide whether a given preparation shows antiseptic or germicidal action. Furthermore if two or more bacteriologists, working independently, would carry out tests on the same product, it would be impossible for them to use such methods as would insure the same or comparable results. It cannot be the purpose of this or any other bill to facilitate such a highly unsatisfactory, unscientific, and confusing situation. But this is exactly what would happen if either the present language of paragraph (j) of section 402 or the proposed language of the Food and Drug Administration were to appear in the law.

In considering this matter it must be remembered that the action of the products covered by paragraph (j) is directed against germs, i. e., against living organisms. It is well known to all familiar with the properties of micro-organisms that unless the conditions of their cultivation and those of the experiments in which they are used in testing antiseptics and germicides are agreed upon and fixed in every detail, major discrepancies in the results obtained by two or more bacteriologists will be the inevitable result. Reference should be made here to the statement presented by Dr. Reddish on March 8 which sets forth the reasons why it would seem best to eliminate paragraphs (j) and (k) from S. 5 entirely, leaving such products to regulatory handling under the general provisions for misbranding, adulteration, and false or misleading advertising.

It should be added here that such a procedure would be entirely feasible and that it would enable the Food and Drug Administration to regulate the labeling and advertising of antiseptics and germicides fully as effectively and thoroughly as in the case of other drugs. In keeping with this idea, and for reasons advanced in the statement of Dr. Reddish, it is held again that special provisions for these drugs as contrasted with the large number of different drugs not specifically mentioned is unjustifiable, either in theory or on the basis of past regulatory experience.

The subsequent remarks apply solely if, in view of the several statements made at the hearing, the Committee on Commerce nevertheless should decide that specific provisions covering antiseptics and germicides are indispensable in a bill of this kind. Unfortunately, since the subject under consideration is decidedly a technical one, it will be impossible to discuss it without the use of some technical language.

The various products which it is the intent of paragraph (j) of section 402 to cover are required at the present time to have such potency as would be sufficient to kill in vitro a resistant culture of staphylococcus aureus, at body temperature under definite and detailed conditions. Reference to the statements presented by Professor Prescott and Dr. Reddish (who, by the way, is the originator of the methods of testing antiseptics and germicides now used by the Food and Drug Administration) will disclose the severity of this method of test. In their proposed wording for paragraphs (j) and (k), Professor Prescott and Dr. Reddish specify the conditions under which such products should be and are now being tested, with the greatest possible accuracy and in such manner as to justify the inclusion of this descriptive language in this bill.

In an informal discussion, the representative of the Food and Drug Administration objected to the wording recommended by Professor Prescott and Dr. Reddish. He thought that the suggested language was too technically involved and he expressed the fear that such a definite stipulation of all the conditions of test would prevent future progress by eliminating the possibility of the adoption of new and better testing methods, as they may become available in the course of time. However, it is held that both these objections are not well founded. So far as the former objection is concerned, certainly it is more important that the language covering the regulatory handling of the products in question should be clear and definite to those who are entrusted with their testing, rather than to the laymen who have no interest in the technicalities involved nor the capacity to grasp all their import. As to the second objection, the wording of paragraphs (j) and (k), as submitted by Professor Prescott and Dr. Reddish, cannot have any bearing either upon the promotion or the retardation of progress in this field. Its purpose is solely to set forth the methods which have been used by the Food and Drug Administration for the past 10 years and which in the predominant opinion of bacteriologists and of other scientific workers give a very satisfactory idea as to the presence or absence of antiseptic or germicidal properties in products for which such properties are claimed. In other words, it is felt very strongly that any product which fulfills the very severe requirements of the testing methods now in use by the Food and Drug Administration, and made a part of Professor's Prescott's and Dr. Reddish's proposed wording for the paragraphs in question, is fully entitled to being classified as an antiseptic, germicide, bactericide, or disinfectant, as the case may be.

Various methods of test may contribute confirmatory evidence in support of the claims made for such products. But no useful purpose is served by leaving the testing procedure open to choice of the regulatory office since such choice would represent an act of arbitrary interpretation by the individual enforcing

officer. In this connection it should be added that apart from the methods now used by the Food and Drug Administration, there exist no other testing methods which are equally acceptable to bacteriologists everywhere as general testing procedures.

Reverting to the language proposed by the representative of the Food and Drug Administration, it is held in conformity with the ideas expressed above that it would be reasonably acceptable (though definitely less satisfactory than the wording suggested by Professor Prescott and Dr. Reddish) only if amended in the following manner:

SEC. 402. A drug shall be deemed to be misbranded—

(*j*) If it purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic for any use on or within the body and its labeling fails to bear plainly and conspicuously adequate directions for such use, and when used as directed, it does not have the germicidal effect upon staphylococcus aureus equivalent to that of a one to eighty dilution of phenol for ten minutes at thirty-seven degrees centigrade, both to be tested by the same standard in vitro method: *Provided*, That no drug shall be deemed to be misbranded under this paragraph by reason of (1) failure of its labeling to bear adequate directions for any advertised use if such advertising is disseminated only to the medical and pharmaceutical professions or (2) its failure to have the germicidal effect required by this paragraph if its own standard of such effect is stated on its labeling or in its advertising, if such advertising is disseminated only to the medical or pharmaceutical professions.

The above amendment, of the most recently suggested wording of the Food and Drug Administration specifies a definite test micro-organism, provides sameness and uniformity of the testing methods, and requires the use of in vitro procedures.

It may seem unnecessary at this time to stress the importance of specifying a definite micro-organism, as this matter has been gone into in some detail in Professor Prescott's and Dr. Reddish's statements. By way of a brief justification it may be said, however, that staphylococcus aureus has been specified because of its ubiquitous distribution, general pathogenicity, and its great resistance to antiseptics.

We feel that a 1 to 80 aqueous solution of phenol is a perfectly proper standard for evaluating antiseptics and germicides provided a definite micro-organism is also specified. The reasonableness of such a requirement is obvious when one considers the vast number of chemical compounds and substances used as germicidal agents and the vastly different way in which they react with the great number of varying kinds of micro-organisms. It is entirely improper to require any germicidal agent to have exactly the same germicidal effect as 1 to 80 solution of phenol regardless of the type of organism particularly as many organisms are of no importance in the specific conditions which require treatment with antiseptic or germicidal agents. It would be absurd, for example, to forbid the sale of an effective germicidal mouth wash simply because of the fact that it would not have the same germicidal effect upon the organisms causing athlete's foot as might be possessed by a particular solution of phenol.

The importance of emphasizing the sameness of the testing method for a comparison of antiseptic and germicidal effect of a given product with that of phenol is obvious to everyone familiar with this problem. Repeating, in this connection, what has been said before, the present methods of testing antiseptics and germicides are so severe that any product that fulfills their requirements is entitled to classification under one or more of the four terms, the use of which paragraph (j) undertakes to regulate. It is entirely unnecessary and scientifically insupportable to leave the language so indefinite as to allow at some future time and by an arbitrary act for the testing of the claimed antiseptic action of a given product by one method and for that of the phenol standard by another, different method. Both the present language of paragraph (j) and the new proposed language of the Food and Drug Administration would allow for just such an arbitrary interpretation unless amended as suggested above.

The phrase "in vitro" was used in the amended wording in order to insure the uniformity and reproductibility of results. As pointed out above, even the use of such simple, single-celled organisms as bacteria require a very complete and detailed statement of the conditions of test; yet the indefinite wording of both the original paragraph and of the proposed paragraph pre-

pared by the Food and Drug Administration would not exclude the introduction of methods other than the so-called "in vitro" methods of the bacteriological laboratory.

More particularly it would allow for the application of so-called "in vivo" methods, which call for the use of the animal or human body. It is realized that, e. g., for clinical purposes such experiments on the animal or human body are justified, because they may supply added information in specific instances. But it is well known that in such complicated organic structures as are represented by the animal and human body there are great individual variations which would complicate the testing of preparations for general use, such as those comprised by the paragraphs in question. The introduction of such variables would result in the creation of a most confusing situation; yet it would be quite possible under the present wording and also under the unamended wording of the paragraph suggested by the Food and Drug Administration.

There is a final objection to the wording under "*Provided*, (2) Its failure to have the germicidal effect required by this paragraph if its own standard of such effect is stated on its label and such drug is distributed for use solely by the medical profession." This matter has been discussed with representatives of the Food and Drug Administration, and we believe that we are entirely in accord as to the principles involved. The language is objectionable in that it would permit the labeling of preparations for specific uses as, for example, for the treatment of gonorrhea, which might get into the hands of the public and therefore be decidedly objectionable from the standpoint of public policy. It is believed that the modification suggested above meets all of the necessities of the situation and will be approved by the Food and Drug Administration.

By way of summary the Committee on Commerce of the United States Senate is respectfully requested to consider the following possibilities concerning paragraphs (j) and (k):

(1) Complete deletion of paragraphs (j) and (k) as superfluous for the purpose of this bill.

(2) Adoption of the wording of paragraphs (j) and (k) as presented by Professor Prescott and Dr. Reddish in their respective statements before the subcommittee, if in the opinion of the committee their deletion is unfeasible or undesirable.

(3) Acceptance of the most recent wording of the Food and Drug Administration with the amendments herein above suggested.

JOHN H. WRIGHT, *Secretary,*
Chairman of the National Committee of Manufacturers of Antiseptics.

Senator GIBSON. Mr. W. B. Robinson.

STATEMENT OF W. B. ROBINSON, REPRESENTING THE DR. NATHAN TUCKER LABORATORY

Mr. ROBINSON. Our formula is property and it has as definite a money value as has a piece of real estate.

It is unfair—it is dishonest to take from us our property either in whole or in part. Taxation is legal—confiscation is unjust.

Medicine has made marvelous progress—yet we know less about the physiological and therapeutic affects of drugs than of any branch of our art.

The name of the ingredients will convey but little information to the average physician and none to the average layman.

Allergy? To be consistent—require that a notice be sent ahead each time a horse is to pass through the State and attach a warning to each piece of bread and pastry.

Senator COPELAND. The chairman asked me to call next Mr. C. W. Godefroy.

STATEMENT OF C. W. GODEFROY, DIRECTOR OF THE LEGISLATIVE DIVISION OF THE NATIONAL HAIRDRESSERS AND COSMETOLOGISTS' ASSOCIATION

Mr. GODEFROY. I asked to file a brief here on behalf of the National Hairdressers and Cosmetologists' Association. I do not wish to take the committee's time except to stress regarding the definition of cosmetics and drugs. Cosmetics, we should like if possible to confine to beauty preparations. We should suggest the putting of devices in a separate classification. We concur with the previous witnesses in that.

Senator COPELAND. The last witness spoke of that, or was it Miss Wall?

Mr. GODEFROY. Miss Wall spoke of that. She suggested putting the word "devices" in cosmetics.

Senator COPELAND. Have you the language that is necessary?

Mr. GODEFROY. I have in this statement here some suggestions.

Senator COPELAND. That you are filing for the record?

Mr. GODEFROY. Yes.

Senator COPELAND. But you have there the language that you suggest?

Mr. GODEFROY. I have in some cases.

Senator COPELAND. We will be glad to have that in the record.

Mr. GODEFROY. We also feel the definition of advertising is inclined to be too severe, inasmuch as some substances which we will call cosmetics are classified as "drugs" in this bill. If they could be classified as "cosmetics", perhaps it will be different.

We also feel that the liability to the retailer on a broadcast is unreasonably severe. He has the right to use other forms. He is usually intrastate commerce, and to make him responsible for his broadcast, which is an exception to the exception, we feel would be a rather great hardship on him.

Senator COPELAND. I believe it was Mr. Bellowes who spoke about that. Did you hear his testimony?

Mr. GODEFROY. I heard practically all of the testimony, Senator.

Senator COPELAND. I take it then that what Commissioner Bellowes said is in harmony with your views.

Mr. GODEFROY. I feel so. And then finally, I beg to say, not being a lawyer——

Senator COPELAND (interrupting). That gives you good standing here. [Laughter.]

Mr. GODEFROY. I am one of this profession. I have a small manufacturing concern growing out of beauty shop also, so I speak partly for myself. There is one point in the bill that we think is capable of being ambiguous. It is section 305, page 11, beginning on line 13, which relates to emergency permit control. It deals with the places where foods are manufactured and processed. And we note that on page 21 beginning with line 23, section 711, there is used language relative to seizures of any article of food, drug, or cosmetic. Then note that the language on page 42 goes on to permit the seizure of "articles which did not, at the time of manufacture, processing, or packing, hold an unsuspended valid permit, if so required by

regulations under section 305." We suggest the insertion of the words "of a food" on page 42, line 1, between the words "or" and "that", so that that portion which follows and which relates to section 305 be clarified so as not to imply that the emergency permit control be intended also to cover cosmetics, and drug-manufacturing processes, and so forth.

Senator COPELAND. Let me get that point. That was on page 41.

Mr. GODEFROY. Page 41, yes; section 711, line 22.

Senator COPELAND. And your suggestion was what?

Mr. GODEFROY. On page 42, which is the continuation of that section, at the very end of line 1, between the words "or" and "that", there be inserted the words "of a food."

Senator COPELAND. I see.

Mr. GODEFROY. And, finally, we should like to see certain exemptions for cosmetic weight, following presumably the New York State law, the exemptions possibly as Mr. Mark said for fancy packages which are sold as gifts or as articles somewhat along the line of art as well as for their contents, and then if coal-tar colors have to be included——

Senator COPELAND (interrupting). I want the reference there. Have you the reference?

Mr. GODEFROY. Yes; I have the reference. I thought to save time——

Senator COPELAND. No; I would like to have the reference if you do not mind.

Mr. GODEFROY. On page 22, line 7.

Senator COPELAND. Yes; I remember Mr. Mark made some suggestion there. What is your suggestion?

Mr. GODEFROY. On page 22, line 7, we concur with the previous witness, and I mean Mr. Mark, that exemptions as to weight and measure and so forth, branding, he made for fancy packages which are sold for their artistic beauty as well as for their contents. We suggest specifying in the bill a minimum exemption as to sizes, borrowing the idea from the New York weight and measures law.

Senator COPELAND. Very well.

Mr. GODEFROY. Then, finally, as to the matter of coal tars in drugs, coal-tar colorings, we concur with Dr. Craig, I think his name is, this gentleman here [indicating], who made the suggestion that in line 16 on page 13, the words be inserted after the word "contains"—"for the purpose of coloring."

Thank you.

Senator COPELAND. Much obliged to you. You may file your brief.

BRIEF FILED BY C. W. GODEFROY, DIRECTOR LEGISLATIVE DIVISION, ON BEHALF OF THE NATIONAL HAIRDRESSERS' AND COSMETOLOGISTS' ASSOCIATION

The National Hairdressers' and Cosmetologists' Association is composed of affiliated State and local associations, dedicated to the interests of the beauty-culture industry, and the so-called "beauty shop." Although a beauty shop is primarily a service institution, its interest in S. 5 is keen for various reasons. A beauty shop acts as a merchant, therefore would be responsible for goods affected which it buys either for use or for sale; it would be responsible for results in its professional work arising from a disturbance in the goods due to effects brought on by the law.

In some cases a beauty shop would come under the classification of "manufacturer" under the law since many shops make a lotion, cream, tonic, shampoo, etc., for professional use or for sale in their establishments. In some cases these are sold to other shops or to ultimate consumers, at times across State lines. The beauty shop is not unmindful of the benefits to be derived from proper regulation, as testified by the fact that 34 State laws regulating beauty culture were passed through the initiative of the organized cosmetologists.

"DRUG" DEFINITION TOO BROAD

Our primary interest in S. 5 is beauty preparations. We submit that the definitions found in section 201 do not properly segregate them. Certain of such articles are included under the definition of "drugs." We submit that the public would be equally well protected and the industry benefited were the suggestion of a previous witness to be accepted by your honorable committee, namely, that the words "and cosmetics" be inserted in line 14 of page 2, so that, as amended, beginning with line 12, this portion read: "* * * and (3) all substances, preparations, and devices, other than food, and cosmetics * * *."

We also submit a similar amendment in line 11 of page 2, after the word "devices", providing the definition of "cosmetics", is amended as noted in the following. The relevant part (beginning with line 10, page 2), as amended, will read: "* * *; and (2) all substances, preparations, and devices, other than cosmetics, * * *."

REWORD DEFINITION OF "COSMETIC"

As to the definition of the word "cosmetic," we concur with a previous witness in that it be made to include preparations intended for beautification but which, due to the broad definition of "drugs", are classed as such under the present draft—such articles, for example, as hair tonics, certain creams, depilatories, deodorants, and so forth.

In the beauty shop, the word "treatment" is employed for lack of a proper word appearing to be available. As used in the beauty shop, the word "treatment" is limited to manipulations with or without the use of preparations, intended solely to promote the good grooming, appearance of, or attractiveness of the patron, in contradistinction to the use of the word "treatment" signifying the work of the medical profession. Licensed cosmetologists in the various States are possessed with knowledge due to the course of education imposed by law whereby diseased conditions may be recognized and refused. Further, the standard of education is constantly being raised by amendments in the various States, to include high school, graduation, and even a period in college. We submit that cosmetics designed solely for the use in the cosmetological art be wholly classed as "cosmetics" and not also as "drugs."

ADULTERATED COSMETICS CLASSED AS "DRUGS"

Turning to section 401 on page 13, if some preparations we know as "cosmetics" are to be classified as "drugs", we are keenly interested in this "adulterated-drugs" provision. We hold the view that labeling and advertising (lines 7 and 8, page 13) is not a matter of adulteration, but of misbranding and should be so considered. In line 16 of page 13, we concur with a previous witness in that afte rthe word "contains", there be inserted the words "for the purpose of coloration", for the same reasons he enumerated.

MISBRANDING THOSE COSMETICS CLASSED AS "DRUGS"

If labeling and advertising will be considered as misbranding, as submitted in the foregoing, we suggest that the relevant matter in section 401 (a) (1) be written into section 402, which section deals with misbranded "drugs". However, we submit that the definition as to what is a "misbranded drug" is too severe. Page 15, line 10, uses the language "misleading in any particular". We submit that misleading is a matter of understanding over which the originating party has not absolute control. We suggest that this be qualified and become "any material particular".

Further on in the same section and paragraph, we suggest that the word "sustained" in line 13 (p. 15) be changed to "supported" and that "substantial" in line 14 be changed to a word less comprehensive, such as "reliable", so that a misbranded cosmetic which was classified as a drug could not be one, the claims of which were supported by demonstrable scientific facts or reliable medical opinion.

ADULTERATED COSMETICS

Coming to section 501 which deals with adulterated cosmetics, we feel that the word "may" in line 25 of page 20 is far too comprehensive; we suggest that it be dropped and the relevant matter be made to read in the indicative—"which renders it injurious"—this primarily because the bill does not seem to contain any provision taking note of the effect on abnormal individuals. We concur in the recommendation of a previous speaker that such be written into it.

Paragraph (e) of section 501 (see p. 21, line 17) is new and deals with coal-tar colors. We make the same recommendations that we made for them in the case of drugs, namely, that in line 17, after the word "contains", there be inserted the words, "for the purpose of coloring * * *." We suggest the addition of an enabling provision whereby intermediates which are not colors but which produce colors be covered, such as, for example, in the manner which they are controlled under the New York City code which, we feel, protects the public and is not an unreasonable hardship on the manufacturer or the beauty shop.

Section 502 (a) defining misbranded cosmetics uses the unqualified term, "misleading in any particular". (See p. 21, line 23.) We suggest that this be made to read in any particular relevant to the act, for what is "misleading" is not under absolute control of the originating party.

COSMETICS NOT SOLD BY WEIGHT OR MEASURE

On page 22, line 7, we concur with a previous witness that exemptions as to weight, measure, etc., branding be made for fancy packages which are sold for their artistic beauty, as well as for their contents. We suggest specifying in the bill the minimum exemptions as to sizes, borrowing the idea from the New York weights and measures law.

FALSE ADVERTISING

On page 24, lines 4 and 5, we suggest the same amendments as we did for the similar section to be found on page 15—lines 13 and 14—so that a cosmetic, the claims of which are supported by demonstrable scientific facts or reliable medical opinion shall not be classed as falsely advertised. Further, we hold no brief against false advertising enforcement being under the jurisdiction of the Federal Trade Commission, as has been recommended by previous witnesses. The public is just as much concerned if an article of furniture or clothing is falsely advertised as whether it be a drug or cosmetic, and it seems logical that that agency of the Government dealing with false advertising handle drug and cosmetic false advertising too.

BROAD ADMINISTRATIVE POWERS

We concur with a previous witness in that section 701 (a) (see p. 25, line 4) seems possible of broad interpretation, vesting unreasonable legislative powers in the hands of the same agency which is to act as prosecutor. This is especially true since paragraph "(f)" states that action by the committee evidently provided as a safeguard may be taken without its having to convene. (See p. 30, line 16.) From a practical standpoint, we submit that this would result in too much danger of the committee members giving insufficient consideration to differences of opinion with the result that they tend to become mere "rubber stamps."

RETAILER'S RESPONSIBILITY FOR RADIO BROADCAST

Section 708 (e) contains an unusual provision insofar as a retailer is concerned. It begins on line 8 of page 39. Because of it, if he were to broadcast an advertisement of any article not sold in interstate commerce by himself or others, even though the broadcast were worded in good faith, he would violate the act. We submit that this broadcast exemption is unfair to the retailer and should be stricken out.

Finally, we respectfully call attention to what we believe to be an ambiguity in the bill: Section 305 (p. 11, beginning with line 13) relates to emergency permit control. It deals with places where foods are manufactured or processed. Note that on page 41, beginning with line 23, section 711, there is used language relative to seizures of any article of food, drug, or cosmetic. Then note that the language on page 42 goes on to permit seizure of articles "which did not, at the time of manufacture, processing, or packing, hold an unsuspended valid permit, if so required by regulations under section 305." We suggest the insertion of the words "of a food" on page 42, line 1, between the words "or" and "that", so that that portion which follows and which relates to section 305 be clarified so as not to imply that the emergency permit control be intended also to cover cosmetic and drug manufacturing, processing, etc., plants, for in our case this would include a good portion of the estimated 60,00 beauty shops operating in the United States.

Senator COPELAND. Dr. Fischelis.

Dr. ROBERT P. FISCHELIS. Yes, sir.

Senator COPELAND. Doctor, haven't you already testified?

Dr. FISCHELIS. I spoke on the variation clause. I have something else that I want to present.

Senator COPELAND. What are you bring up today? The chairman told me that the witnesses who have testified be permitted to extend their remarks, but he did not want to put them on a second time. What is it you have today?

Dr. FISCHELIS. My argument here today is principally on the variation clause, and I would like to answer one or two statements that were made yesterday.

Senator COPELAND. You mean regarding the variation clause?

Dr. FISCHELIS. That is one of the things; yes.

Senator COPELAND. What was the other one? Antiseptics?

Dr. FISCHELIS. No; I do not intend to speak on antiseptics at all. I would like to point out to the committee the way in which the drug industry is represented on some of these controversial matters, that is who constitutes the groups that are speaking for and against some of these matters like the variation clause, so that it is clearly in the mind of the committee as to what percentage of the industry is clearly represented.

Senator COPELAND. Have you prepared what you have to say on the variation clause?

Dr. FISCHELIS. I have my notes.

Senator COPELAND. I had pretty definite instructions from Chairman Clark about repetition. It was understood, Doctor, and it is now, that anything that you or any other person desires to present for the record will be received, and you must bear in mind that what we are doing here is simply preparing a record for the Senate. So if you could prepare that and put it in the form of a statement, if I am not asking too much of you, I would be keeping faith with the chairman if you were permitted to file that.

Dr. FISCHELIS. I will be perfectly willing to file what I have to say. I do feel, however, that in view of one or two statements that were made yesterday—and I was referred to yesterday in some of the testimony as perhaps not representing the views——

Senator COPELAND (interrupting). If you are making a personal defense, go ahead.

Dr. FISCHELIS. I would like before I do that, Mr. Chairman, to present on behalf of two organizations, short statements that they would like to have included in the record. One is from the Philadelphia Association of Retail Druggists, and the other is from the New Jersey Pharmaceutical Association.

Senator COPELAND. They may be included in the record.

BRIEF OF THE PHILADELPHIA ASSOCIATION RETAIL DRUGGISTS, TO THE CONGRESS OF THE UNITED STATES

Whereas it has become apparent that in order to afford adequate protection to the consuming public against fraud and deception, the Food and Drug Act now in effect needs to be expanded and strengthened; and

Whereas several bills have been introduced in the Congress which are designed to achieve the above purpose: Therefore be it

Resolved by the Philadelphia Association of Retail Druggists in regular meeting assembled, That we endorse any legislation which provides adequate protection against the distribution of substandard or adulterated foods and drugs; and be it further

Resolved, That such legislation should provide methods for preventing the exploitation of foods and drugs and cosmetics by false, misleading, and deceptive advertising in whatever form; and be it further

Resolved, That such legislation should require statements on the labels of containers, setting forth the identity and percentage of the patent ingredients contained therein; and be it further

Resolved, That enforcement of the foregoing and all other provisions of food- and drug-control enactments should be placed under the jurisdiction of the Food and Drug Administration in the Department of Agriculture.

BRIEF OF NEW JERSEY PHARMACEUTICAL ASSOCIATION

The New Jersey Pharmaceutical Association favors legislation, both National and State to revise the food and drug laws which revision shall embody the following twelve point program:

1. That no drug or medicinal preparation recognized as such in the U. S. P. or N. F. shall be sold or advertised for sale under any other name than that recognized by the U. S. P. or N. F.; and that such drugs or medicinal preparations shall meet with the strength, identity, or purity as determined in the tests laid down by the U. S. P. or N. F. official at the time such drug or medicine is sold.
2. That drugs or medicinal preparations which are sold or advertised to the public for use by them and which drugs or medicinal preparations are not official in the U. S. P. or N. F., shall bear on the label the name of the drug, if a single drug, or drugs if a preparation.
3. Prohibition of false and misleading advertising, such advertising to include all forms of advertising, whether printed, including labels, circulars, newspapers or magazines, or whether by word of mouth including radio.
4. Inclusion of cosmetics in the revised food and drug legislation.
5. Provisions for precautionary statements on labels of drugs liable to deterioration.
6. Provisions for the safety of self-medication by preventing medicines from being sold as cures unless they are cures.
7. Provisions for explicit directions for the use of advertised medicines plainly stated.
8. Provisions for requiring that drugs or medicinal preparations containing habit-forming drugs, including hypnotics, shall bear warning labels, and shall be sold at retail only by registered pharmacists.
9. Provisions that claims for therapeutic effects of medicines not only be true, but also be not misleading.
10. Provisions that antiseptics shall have actual germicidal power.
11. Provisions for restraining repetitious offenses.
12. Provisions to restrain the imitating of other products and the counterfeiting or imitation of labels or identifying names of other products.

Adopted January 30, 1935 at final session of annual convention in Jersey City, N. J.

Dr. FISCHELIS. It seems in view of the conflicting and possibly erroneous statements representing professional pharmacists in the drug industry, that the committee should be informed as to the type of interest represented and the extent to which they reflect pharmaceutical opinion—

Senator COPELAND (interrupting). What you are saying now, Doctor, is because of the fact that your name was used yesterday and this is in reply?

Dr. FISCHELIS. Yes, sir.

Senator COPELAND. Because I could not keep faith with Senator Clark if I permitted you to make a new statement, but you have been referred to and you feel that you should make a statement regarding that, and certainly I could not object to its being received.

Dr. FISCHELIS. I can confine myself then to this matter entirely.

Senator COPELAND. I wish you would.

Dr. FISCHELIS. Mr. Bigelow, who spoke for the American Drug Manufacturers' Association yesterday, when asked to comment by Senator Copeland on the opinion expressed by several witnesses before the committee, including myself, with respect to the variation clause stated that Dr. Beal, who is a member of the council of the American Pharmaceutical Association, disagreed with my stand that lines 10 to 18 at page 14 of Senate 5, Committee Print 3, should be eliminated. That is the variation clause.

Dr. Beal is a highly respected and most able member of our association. In this instance, however, if Mr. Bigelow is quoting Dr. Beal's opinion correctly, and I presume he took pains to ascertain Dr. Beal's opinion, before quoting him, Dr. Beal does not speak for the American Pharmaceutical Association, for the American Pharmaceutical Association expressed itself very definitely on the subject by resolution at its convention in 1926 as follows:

It is noted that there is an increasing disposition on the part of manufacturers to use labels which are similar to U. S. P. and N. F. titles for preparations, both sub-standard and above standard, whereas such practice is not only deceptive for the buyer but carries potential dangers for the user; we emphatically protest against the use of U. S. P. and N. F. titles for any preparations excepting those which are prepared exactly according to U. S. P. and N. F. formulas.

No official expression since 1926 has been recorded by the association to alter its stand on this question, and therefore, while in this instance I have also expressed my own views on the subject, I really placed before the committee the expressed view of the association, and I speak for it as its president. In this connection, and in view of the fact that the committee will have before it the record of the hearings last year when considering this year's legislation, I deem it necessary to point out that the testimony given by Dr. Beal last year was given as spokesman for the National Drug Trade Conference and not as spokesman for the American Pharmaceutical Association.

The American Pharmaceutical Association did not have a separate spokesman last year at the hearings on S. 1944 and S. 2800. The National Drug Trade Conference made up of delegates from the American Pharmaceutical Association, National Association of Retail Druggists, National Wholesale Druggists Association, Federal Wholesale Druggists' Association, American Association of Colleges of Pharmacy, National Association of Boards of Pharmacy, American Drug Manufacturers' Association, American Pharmaceutical Manufacturers' Association, and Proprietary Association, appeared in opposition to these bills last year, although a separate statement

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favoring S. 2800, with certain modifications, was made on behalf of the American Association of Colleges of Pharmacy. It is conspicuous by its absence this year, a fact which can probably be best explained by the president of that organization who is also secretary and executive vice president of the American Drug Manufacturers' Association, the same association of which Mr. Bigelow is the general counsel.

Incidentally, Mr. Bigelow referred to Dr. Beal as chairman of the revision committee of the United Stataes Pharmacopœia. This was an error. Dr. Beal is not chairman of the revision committee which produces the Pharmacopœia. He is chairman of the board of trustees of the U. S. P. Revision Convention. This board has charge of the fiscal affairs and not of the revision.

Now, Mr. Chairman, the balance of what I have to say bears on the variation clause and is in reply to Mr. Bigelow's statement with regard to its effect upon manufacturers.

Senator COPELAND. That you will prepare for us and we will put it in the record.

Dr. FISCHELIS. If you prefer to have it done that way, I will do so.

(The matter referred to is as follows:)

It seems to me that in view of a number of conflicting and possibly erroneous statements made at these hearings in behalf of interests representing professional pharmacy and the drug industry, the committee should be informed as to the type represented and the extent to which they reflect pharmacal opinion in the matters under discussion.

The American Pharmaceutical Association, of which I am president, is the oldest pharmaceutical association in the United States. It was organized in 1851 and is all-inclusive in its membership. Manufacturers, wholesalers, retailers, college professors, law enforcement officers, and pharmacists in Government services are all eligible to membership in the association. The association was organized primarily to cope with the problem of adulterated drugs, which was a very serious matter in the days before State and Federal legislation on the subject. Although its individual membership list is not large, it is very representative. Resolutions passed by the association are the expression of its house of delegates, which is made up of delegates from the 48 State pharmaceutical associations, the national associations representing wholesale, retail, and manufacturing interests, Government services, and various separate groups organized to serve the specialized interests within the profession and the industry. All are entitled to send delegates.

Its expression of policy, therefore, reflect as nearly as possible the composite of all shades of opinion within the profession and industry.

In addition to the American Pharmaceutical Association, we have a variety of national organizations representing specific interests within the profession and industry.

The American Association of Colleges of Pharmacy, the National Association of Boards of Pharmacy, together with the American Pharmaceutical Association, are the groups within the profession and industry that compare with the American Medical Association, the American Public Health Association, and similar bodies in their interest in the legislation before your committee from the public health standpoint.

The National Association of Retail Druggists is the trade association of those engaged in the retailing of drugs and medicines and the compounding of prescriptions. Its membership has a dual interest in pharmaceutical affairs. It cooperates actively with the American Pharmaceutical Association in professional matters, and in addition it maintains its own bureaus and committees which look after trade interests.

The American Drug Manufacturers' Association, as Mr. Bigelow stated, represents manufacturers of products used in the compounding of prescriptions and by physicians in their dispensing. Mr. Bigelow, however, neglected to point out that some members of his association are dealers in crude drugs which are sold to patent medicine manufacturers for the compounding of their products, and that it also includes chemical manufacturers who furnish the patent medicine industry with the crude materials entering into their preparations. Furthermore, some of the members of this association manufacture patent and proprietary medicines for those engaged in the patent and proprietary medicine business.

The American Pharmaceutical Manufacturers' Association consists largely of manufacturers preparing medicines for dispensing by physicians, although it also includes specialty manufacturers whose products are supplied to pharmacists for prescription compounding and who also manufacture medicines for others.

The National Wholesale Druggists' Association includes the so-called "service jobbers." They are the independent wholesale druggists who supply retail druggists with stocks of patent medicines and other drug-store commodities. A very large part of the business of the members of the National Wholesale Duggists' Association is, naturally, in advertised medicines, and they are the distributors to the retail drug trade of practically all patent medicines.

The Federal Wholesale Druggists' Association is the association of cooperative wholesale drug houses. These cooperatives are, in many cases, owned by retail druggists as stockholders, and they, likewise, act as distributing organizations for patent medicines and other drug-store commodities.

The Proprietary Association and the United Medicine Manufacturers' Association are national organizations representing manufacturers of medicines advertised and sold to the public, usually without medical advice. They represent the so-called "patent medicine industry." Some of the members of these associations are actually manufacturers of the preparations which they market. Others merely package, advertise, and distribute their remedies and have them manufactured by members of the American Drug Manufacturers' Association or similar concerns. Still others are merely advertisers and distributors of the remedies which are manufactured for them.

In speaking for a specific group in the industry, a representative may refer to the number of units represented or the volume of business represented. The largest group in the profession and industry is made up of registered pharmacists who either own retail drug stores or are employed to carry on professional pharmaceutical activities in laboratories of retail pharmacies, manufacturing houses or in Government laboratories. They total about 130,000 individuals. There are about 55,000 retail drug stores. Their interests are represented largely by the American Pharmaceutical Association and National Association of Retail Druggists, and they distribute roughly 90 percent of all drugs and medicines consumed by the public. They are, therefore, closer to the public than any other group in the industry and most interested in the health and welfare of the average citizen as far as the sale of drugs and medicines is concerned. Their viewpoint as to the need for the public control of the industry is, therefore, an important one and less tinctured with self-interest insofar as this particular legislation is concerned. May I remind you that they favor S. 5 with advertising under the jurisdiction of the Food and Drug Administration, formula disclosure and no variation clause in the case of the American Pharmaceutical Association.

Mr. Bigelow, in his testimony yesterday, quoted from correspondence with Mr. Lynn, of Eli Lilly & Co., whom he referred to, incorrectly I believe, as president of that firm. According to my information, Mr. Eli Lilly is the president of that company and Mr. Lynn is its general manager. In this correspondence it was asserted that the U. S. P. and N. F. originate nothing and there was at least a strong intimation that formulas and names originated by manufacturers had been appropriated by the compilers and revisers of the U. S. P. and N. F. This is a gratuitous insult to the medical and pharmacal professions, for it is a well-known fact that many of the drugs and preparations now listed in these official standards were there before any drug manufacturing firms, such as Mr. Bigelow represents, came into existence. The policy of the U. S. P. and N. F. revision committees is to include no drugs in these books which have been patented, unless the patents have expired. It is a further policy not to list drugs in these standard works under registered trade-mark names, even though the patents on these drugs have already expired. Thus in the case of acetyl-salicylic acid, now listed in the U. S. P. since the patent on it has expired, it is not listed under the name of aspirin or any other trademarked title, but under its chemical name only.

Mr. Bigelow also alluded to the fact that Eli Lilly & Co. had donated to public use its patent for compounding a solution of ephedrine in mineral oil

by the intervention of oleic acid as a solvent in the form of a vegetable oil. He did not point out, however, that the effect of this patent, if enforced, might have been to prevent the compounding of physicians' prescriptions for ephedrine in mineral oil by the method covered in this patent and that the indignation of the pharmacal profession in learning of this possible restriction had reached the point, in some quarters, of considering a court test of the validity of the patent. The action of Eli Lilly & Co. in surrendering its patent to public use was, therefore, not only timely in their own interest, but fair, as well, to the profession. The issuance of a patent on this process by the United States Patent Office was of doubtful legality in the opinion of many members of the pharmacal profession. In making available its patent on the ephedrine spray solution, Eli Lilly & Co. did not surrender the trade name of its product. The fact is that practically every one of those manufacturers who develop some kind of a formula gives it a trade name which is registered, if possible. As soon as one firm brings out a formula like that of the ephedrine spray, the others supply a similar formula with another trade name. A mere glance at the trade-name list issued by the American Drug Manufacturers Association will convince anyone that these manufacturers have been given every opportunity to protect their special formulas by trade marks. It is simple justice and fair play for the American people to keep the names under which standard formulas are listed in the U. S. P. and N. F. exclusively for the designation of those products which comply absolutely with such standards.

The elimination of the variation clause is in the interest of honest manufacturing and dispensing of drugs and medicines. It will harm no one except the manufacturer who insists on trading on an official and recognized name without supplying the official formula.

If the manufacturer wants to vary the official formula he may do so but he should then select a new name for the product. The U. S. P. and N. F. titles should be a guaranty of identity, purity, and strength, in conformity with official standards from coast to coast and from border to border.

It is regrettable that Mr. Bigelow introduced the correspondence and other references to Eli Lilly & Co. into this record, as this firm has been one of the outstanding contributors to pharmaceutical and chemical research, and has made available, on a commercial scale, some of the most valuable medicinal products of the University Research Laboratories. It is at least doubtful that the principal officers of this firm hold the views expressed by Mr. Bigelow and the gentleman he quoted with regard to the U. S. P. and N. F.

In Senator Copeland's State (New York) I believe no variation is permitted and nobody has been put out of business on account of it. Professor Cook raised the question of the constitutionality of the U. S. P. if no variation clause is included in S. 5. If Congress is delegating power illegally by adopting the U. S. P. and N. F. as official standards, it is doing so regardless of the variation clause.

Changes can be made in the organization of the revision convention and committee if necessary to preserve the present status.

Congress could issue the call for the U. S. P. revision convention and make it an arm of the Government if necessary. The revision committee, as now organized, could readily become a revision commission with a proper set-up under governmental auspices and retain the present democratic principle of selecting the committee.

To hold that the constitutionality of the U. S. P. and N. F. cannot be questioned as long as there is a variation clause in the food and drug law is specious reasoning and to threaten to question the constitutionality of these standards, if a variation clause is not inserted in S. 5, is to inject cheap politics into a public-health question.

Senator GIBSON. Mr. W. G. Campbell?

STATEMENT OF W. G. CAMPBELL, CHIEF OF THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF AGRICULTURE

Senator COPELAND. Do you represent the consumers, Mr. Campbell?

Mr. CAMPBELL. I hope so.

Mr. CHAIRMAN. I spoke at length at both of the previous hearings. Most of what I said before, and then, if not everything that I said is applicable in substantial measure to a consideration of the present bill S. 5. I have no desire to repeat the statements I have already made. The committee has indicated that it does not care to have a mere repetition of statements. I have no desire either to speak for the purpose of hearing the sound of my own voice.

I am perfectly willing to submit a statement if that is what the committee prefers, or I am willing to undertake to discuss the various matters that have been brought up as briefly or as exhaustively as the committee wishes.

Senator GIBSON. We feel that if you will submit a statement for the record, that that will be ample.

Mr. CAMPBELL. Very well. That will suit me entirely.

Senator COPELAND. Was Mr. Crawford to be called?

Mr. CAMPBELL. I understand not.

Senator GIBSON. His name is on the list.

Mr. CAMPBELL. I did not understand that he was to be called.

Senator COPELAND. Now, after all of these hearings, have we finished?

Mr. J. B. MATTHEWS. Mr. Chairman, my name was on the list and was not called.

Senator GIBSON. Yes; Mr. Matthews.

STATEMENT OF J. B. MATTHEWS, REPRESENTING THE CONSUMERS RESEARCH

Mr. MATTHEWS. I represent the Consumers' Research with headquarters in Washington, N. J., an organization which does in a very real sense speak on behalf of the ultimate consumer, numbering some 50,000 of them. We have been classified at this hearing by some witnesses as professional crusaders, with such adjectives as "silly" and "hysterical" used to characterize us. If the interested parties testifying on this bill must be reduced to two classifications—and I do not concede that they must be—we prefer to be counted among the professional crusaders who speak on behalf of the consumers rather than to be found among the agents of the modern Borgias of the patent-medicine racket. This bill is, as Senator Copeland has stated repeatedly, a measure designed to protect the consumers. It is that if it has any meaning at all. Yet it is perfectly clear that there are industries who would like to prevent the consumers' case from being presented here. I have before me a copy of Business Week of February 23, 1935, a responsible business organ published by the McGraw Hill firm—I believe the most powerful business publishers in America. This journal has the boldness, the audacity, to claim the support of this senatorial committee in such suppression. I think it highly important that the statement from Business Week be brought to the attention of the committee if the committee has not seen it.

Commenting on the choice of Senator Clark as chairman of this committee—this is not my comment, but I wish only to read the statement of Business Week with regard to the way in which this hearing is to be conducted [reading]:

He——

Senator GIBSON (interrupting). You are reading the statement from the publication?

Mr. MATTHEWS. Yes. [Continuing:]

He—

referring to Senator Clark—

is a high-pressure parliamentarian and can rush the hearings through in 2 days. Industry representatives believe that he will be able to choke off propaganda of the consumer agitation type which was one thing they feared about the hearings.

Senator COPELAND. Of course, you are going to say, I presume, that you know that that could not be true of Senator Clark?

Mr. MATTHEWS. I think Senator Clark would like to have the opportunity of giving his most vigorous condemnation of that viewpoint which is entertained by so responsible a business organ.

Senator COPELAND. In his absence, I want to say that I do not share any such view, neither does any Member of the Senate.

Mr. MATTHEWS. I regret that Senator Clark is not here. I am sure that he would be vigorous in condemnation of such a conception.

The only point which I wish to make in presenting the statement from Business Week is that it is a perfect picture of the conception of government entertained by business interests who have sent their representatives here and at least they have cherished the hope that they would find this committee cooperating with them in the choking off of those who would speak on behalf of the consumers.

Senator GIBSON. You have not observed any such tendency on the part of the committee?

Mr. MATTHEWS. I was not present last Saturday, but from the report which I read in the newspapers, my colleague, Mr. Arthur Kallet, was prevented from completing his statement. However, Senator, I do not intend to submit this statement at this time except as it indicates an attitude on the part of business interests with reference to the procedure of writing such legislation as this.

Senator GIBSON. Let me suggest to you that Mr. Kallet occupied the attention of the committee here for 50 minutes.

Mr. MATTHEWS. I believe, however, that there were some matters which Mr. Kallet was informed were not germane to the discussion, and which were not permitted in the record.

Senator GIBSON. Not germane?

Mr. MATTHEWS. It was so ruled by the chairman of the committee.

I would like to say just a word on that as a principle without any slight reference to personalities or any animus whatsoever.

It is our belief that the set-up in the business world being what it is, we cannot concretely and clearly discuss some of these problems without at times calling attention to the individuals who have become involved in the set-up. That is the only interest whatever we have in calling attention to any personalities who have been involved. We have no hostility toward individual Senators or toward individuals in business enterprises themselves. We do object to the assumptions which are held in the business world generally with reference to Government, with reference to their own prerogatives in such a hearing as this, and it is against that set-up that we wish to enter our very serious protest.

Senator COPELAND. I want to endorse thoroughly what this witness has said in that particular. This committee and various subcommittees and individual members of the Commerce Committee who have been studying this field—I may say because I know—have had in mind, "What can we do to help the public?" We have striven at the same time, if we could, to keep from embarrassing honest and legitimate business, but our first thought, and certainly the thought of the Food and Drug Administration, has been to protect the public.

Mr. MATTHEWS. The committee has certainly listened to lengthy propaganda of the business agitation type, and if I may paraphrase somewhat the statement which is before me in Business Week, there has certainly been no disposition to choke off propaganda of the business type. We ask only that those who do represent the interests of the consumers be permitted to state fully and freely their conceptions of this legislation.

I do not desire at this time to go into any details regarding the bill. I would like to mention one or two matters which have come up in the previous testimony.

The statement was made by a witness this morning that cod-liver oil is vastly beneficial to children. Senator Copeland asked him at the time if that was a well-authenticated statement. I do not know what Senator Copeland had in his mind when he asked the question, but I would like to say for the record that while I am not a medical man, I can read, and some medical documents are perfectly intelligible even to the layman.

There is a vast literature on the subject of cod-liver oil, and very recent tests made at Cornell University by three professors have shown that experimental goats being fed a diet which was varied in such a way as to isolate the effects of the cod-liver oil, dropped dead after 2 or 3 months of such diet with heart lesions. In the report of the Cornell professors, which has been published in scientific documents, the statement is made that cod-liver oil was fed to the experimental goats at levels frequently recommended for human consumption. Having made that statement in the report, it would seem that the professors believed it a relevant statement to make, in spite of the contention which is sometimes made that experiments on goats have no significance whatsoever for human diet.

However, the literature on cod-liver oil and its toxicity goes back at least to 1888 when studies were made on the subject in Norway. Dr. Agduhr has shown from experiments which have been made with children that 21 such children in Norway who were fed cod-liver oil in various forms were all found to be suffering with heart lesions.

This is a matter of vital importance to be brought to the attention not only of this committee but of the public, and the chief obstacle in my opinion which confronts us when we attempt to do this is the immense influence of manufacturers of patent medicines and their undue influence in the press.

A witness also stated that the arsenic content of cod-liver oil is three or four times the legal tolerance of arsenic in spray residues. According to a study by Dr. Mendell—who I believe is one of our foremost authorities in this field—published in the Yale

Journal of Medicine and Biology, the arsenic content of cod-liver oil was found to be only one part in a million, which is less than the arsenic content of the legal tolerance of the spray residues which amounts to something like one part in seven hundred thousand.

The witness gave a very interesting definition—I think one of importance to bring to the attention of the committee—of favorable and unfavorable legislation. He spoke of the present measure as being a favorable measure. He was questioned at some length by Senator Copeland as to what he meant. I think his final definition of an unfavorable measure was this:

> If a measure calls forth righteous indignation from those upon whom it is to operate, it is unfavorable.

In my opinion that would be precisely as though legislation should be enacted touching kidnapers in such a way as not to lead to any emotional antagonism or indignation on the part of kidnapers. I am not, if you please, at this moment comparing the witness who spoke to a kidnaper, but I am pointing out that it is the function of this measure to control, to curb, to regulate industry in the interests of the consumer, and it may well be, I think it undoubtedly will be, true, that if this legislation is effective in such a manner as to protect the interests of the consumers, there will be several righteously or otherwise indignant industries across the country. In fact, even in its present form——

Senator COPELAND (interrupting). I should feel disappointed if that were not the case.

Even if the legislation in its present form should be enacted, it is obvious from testimony which has been given here that some feeling on the matter has been entertained by some industries.

The point which I wish to make in connection with advertising is a recent development in the post office, which I think the committee should consider. The patent-medicine business, at least one part of it, unless my information is wrong, has debased the Post Office Department to the level of an errand boy in various communities for distributing samples of patent medicines. Only a few days ago we received through the mails in Washington, N. J., a sample of Cascarets, not addressed to anyone in particular, but addressed in this fashion: "To the patron of the mail carrier." Now, apparently this firm estimates in some way or determines in some way the number of homes on a given mail carrier's route, and then sends through the mails enough samples of this nostrum to be distributed one at each house.

Senator COPELAND. You know that is a remarkable thing in the law. I never could understand it either, that a publication—I did not know it applied to samples—with 200, I think it is 200 packages, or publications, as you say, samples of stuff——

Mr. MATTHEWS (interposing). These were samples.

Senator COPELAND (continuing). Were sent and distributed. I think that is the number. It is a very strange provision of the law. It helps us a lot when we are campaigning. We can send out our campaign letters here in bunches in that way. But I cannot see any other good from it.

Mr. MATTHEWS. This is the first instance which has ever come to my attention of "sampling" through the mails. On the back of this particular nostrum were the words "Take one tonight." Now, the company being in absolute ignorance of the state of health of the recipients of these various samples, still has the boldness to make such a pernicious distribution of trash, if I may so characterize it, into our homes, by advising that this nostrum be taken as though it were the habitual thing for us to do. I wish to object strenuously to the fact that Post Office Regulations permit that kind of "sampling." I think it might be a matter for the newspapers, if this becomes extensive, to raise the question as to whether or not their field is not being invaded by the Post Office Department.

Senator COPELAND. They would be engaged then in a laudable enterprise.

Mr. MATTHEWS. I think the newspapers might very well become active on it in their own interests as they conceive them.

The objection has been made by these business interests to a strong measure on the ground that it will set up a bureaucracy. Some businesses seem to fear bureaucracy as the devil itself. But as between a bad bureaucrat and a good patent-medicine manufacturer, I think the public consumer's interest is served better by the bad bureaucrat. In fact the bad bureaucrat is bad chiefly when he comes into close contact with the "good" business men. I need not illustrate that at great length.

The ethical standards of the United States Senate once led that body to refuse to seat one Frank L. Smith, from the State of Illinois, a man who had been charged officially with the regulation of the utilities in the State of Illinois, but while he was regulator he received campaign contributions from Samuel Insull, before the collapse of the Insull empire. The Senate considered that sufficient ground for its refusal. I think the Senate was eminently correct in that. Bureaucracies are only dangerous when they come into control of this kind of a subject where business interests can subvert and pervert the interests of the consumers to their own interests. It has been a matter of some wonderment on the part of a large number that officials in the Food and Drug Administration, after their retirement from the Food and Drug Administration, have speedily gone over to the service of patent-medicine men. That I submit does not leave a good taste in the mouth.

If an adequately protective measure for consumers is written by strengthening existing legislation at many points, it will be because the present influences which are here exerted by the business interests, who would like to have choked off some of us, are not felt. If a weak measure is written it will undoubtedly, in my opinion, not be due to any perversion of character of the Senate or any members of the Senate; it will be because they are under the tremendous pressure which we understand too well, which is brought to bear upon them by the representatives of industry and business.

It is my duty to protest finally against the manner in which my colleague, Arthur Kallet, was prevented from giving his testimony as he desired at the last session.

STATEMENT OF ARTHUR KALLET

Mr. KALLET. Mr. Chairman, since I was the only one whose testimony was cut off, I should like the opportunity to add briefly to it at this time.

Senator COPELAND. Mr. Kallet, it would be strictly in violation of what was stated by Senator Clark. But, listen, if you can confine your remarks to the bill before us and to the protection of the public, as you think the public is entitled to be protected, leaving out the personalities, I personally have no objection to your continuing your statement.

Mr. KALLET. Very well, Mr. Chairman.

Senator COPELAND. And now, for various reasons, please be as brief as you can. It is a long time since I had breakfast.

Mr. KALLET. Without making any personal remarks, I do want to say that we have absolutely nothing against you or any other Senator, but we do feel that the kind of set-up that places Senators with certain connections in charge of legislation such as this, or other legislation, cannot give the consumer a good bill. And that, of course, is what we are concerned with.

Senator COPELAND. Let us acknowledge our manifold sins and weaknesses and you go ahead. Now, what have you got to say about the bill?

Mr. KALLET. The statement was made here yesterday by Mr. Elisha Hansen that advertising can be adequately controlled at the present time by the laws already on the books, can be controlled for example by the Federal Trade Commission and by the Post Office. Now, the very fact there is adequate legislation and there are adequate measures by which advertising could be controlled, yet, it is not controlled, and that means we have to look twice at this bill before us. That is, the very fact that the bill extends control to advertising, does not mean that advertising is going to be properly regulated.

One of the representatives of a women's organization, who testified, said she was not concerned about the technicalities of the bill. In a bill in which the business interests have such a large interest in the light of those technicalities as to the public they become very important.

The representative of the American Medical Association pointed out, and I think coming from him it should have great weight, that medical opinion does not mean anything. He pointed out very properly that with the proper scientific facts you could prove anything. Therefore, it is necessary to change the advertising section of the bill so that it will assure——

Senator COPELAND (interposing). Have you a definite suggestion to make about that?

Mr. KALLET. Yes; I have, Mr. Chairman. However, I will send it in. It is included in the bill which we wrote, and which was introduced in Congress last year by Congressman Boland. What we propose is that all advertising claims shall be submitted and approved in advance. We feel that is the only way in which they can be adequately controlled, and that no claims which have not been approved in advance shall not be made.

I want to refer briefly to a couple of other sections of the bill which I think are very important, and this I think, Senator, shows better than anything else the bias of the bill in favor of business interests and against the consumer.

Senator COPELAND. Let us see the reference.

Mr. KALLET. My reference is to section 702: "The District Courts of the United States are hereby vested with jurisdiction, on complaint of any interested person, (1) to restrain by injunction, temporary or permanent, the enforcement by any officer, representative, or employee of the Department of any regulation promulgated as provided in sections 701 and 703 if it is shown that the regulation is unreasonable, arbitrary, or capricious, in the light of the facts are not in accordance with law, and that the petitioner may suffer substantial damage by reason of its enforcement." The business interests with high-priced lawyers and with their excellent lobbies are well able to protect themselves. I think in this bill they are putting an added measure of protection not for the consumer but for business. And you are inviting them to go to the courts and seek to restrain the enforcement of this act.

What I would propose, particularly if you wish to leave that section in there, is that you give your consumers and your consumer's representative the right also to go to court and to seek a court order for the enforcement of certain sections of the act.

Senator COPELAND. Would he not have that under this as it is written?

Mr. KALLET. I do not think so.

Senator COPELAND. Suppose the Department were to promulgate a regulation that you, as a consumer, are felt to be an unreasonable one and an improper one, would you not have a right to go on? I am not asking this for any other reason than to get the truth about it. Would you not have the right to ask a court for interpretation of that?

Mr. KALLET. I am not a lawyer. I do not think we would have such right nor does the right exist theoretically, nor do I think we would be able to exercise it effectively. I think by putting a specific provision for such right in this bill you would be aiding the consumers greatly.

Senator COPELAND. I want to discuss it with you a little bit.

Mr. KALLET. Yes.

Senator COPELAND. Have you the bill before you?

Mr. KALLET. Yes.

Senator COPELAND. Take page 26, line 3; why would you not have the right as a petitioner to appear and say that you suffer in your health or in your welfare?

Mr. KALLET. That refers back to line 21, 702, which says: "to restrain the enforcement." What we are concerned with here is securing the enforcement, not restraining it. My proposal is you specifically extend to the consuming interests the same right that you extend to the business interest.

Senator COPELAND. After the word "restrain" in line 21 "or insure"? I do not know just how you could do that. I am not a lawyer either.

Mr. KALLET. I would be glad to submit that in writing.

Senator COPELAND. I would be glad if you would.

Mr. KALLET. If you care for it.

Senator COPELAND. You know, Mr. Kallett, I assume—I may be utterly wrong, but I do not think I am—it to be the function of the Food and Drugs Administration to protect us, protect the consumer. I assume that they are on guard. They are the people's counsel, and my contacts have been pretty intimate with this administration through a good many years before I came into the Senate as health commissioner. We had a good many contacts with them, and I always found them desiring to protect the consuming public. We have heard lots of testimony here the last few days, and weeks of it last year from the business interests, who felt they were being squeezed by this sort of thing; but yet, after all I have had the feeling all of the time, and still have it, that we are seeking our side of the table to take care of the public, and if we have gone too far in the matter that these people who have been squeezed might say so, just the same as you have the right to say you have not gone far enough, but I take it, as Mr. Campbell has said of this Department, where he has served so ably so many years, that he is representing us, we, the public, not to quote the Constitution if it is not grammatic in my statement, and that is what he is doing. At the same time if it should be inserted in this bill, something along the line you are going to submit the language of, the committee will be glad to consider it.

Mr. KALLET. I take general exception to the old committee set-up which is proposed in this bill, the Public Health Committee, the Foods Committee, and so on.

Senator COPELAND. Have you a suggestion to make as a substitute?

Mr. KALLET. The first objection to this committee set-up is one which was suggested by Mr. Lever earlier, and that is there is no provision for a budget for these committees. Their service has to be voluntary. They have to do these things while they are also carrying on other jobs. And they cannot possibly function effectively nor scientifically.

Senator COPELAND. I will tell you about that, though, if you will let me give you the minds of the committee. The fact that we are setting up this provision carries with it the implication if not the exact words that they will be paid a per diem and so forth, but our thought was that if the President of the United States chose men who would be honored by his selection, that they would be men who would meet as often as they were needed and render their services without compensation, but at the same time, if any critic of the bill thinks that there should be a different set-up, we will give consideration to any plan submitted.

Mr. KALLET. The trouble is that while that is all right theoretically, it does not work. A committee on public health, if it were to function as it would need to function, ought to be a permanent organization with a huge staff. It ought to have a budget as large as the whole present Food and Drugs Administration. It is a big job that needs to be done by such a committee, and if it were set up with adequate budget and adequate controls to assure that the proper individuals were on that committee who could do important work.

Senator COPELAND. You have been fortunate in that you have not tried to get these budgets through and get the appropriations. It is often difficult to get huge sums. I was pained to hear this morning and I think I might say with propriety that the requests of the Department were cut down in the House. I do not say that in disrespect of another body, but it is very difficult to get money.

Mr. KALLET. That directly relates to another proposal which I want to make later. Let me continue with my comments on the committees, and I will come back to that matter of financing.

Even more than to the constitution of this public health committee, I object to the food-standards committee. There, there are 3 representatives of the public, 2 from the Food and Drug Administration, and 2 from the industry. On the surface that looks like excellent protection for the public. They have more representatives than anyone else, but there again the situation would be this, the public representatives would be acting voluntarily without pay and they would be taking time from other work on which they probably depend for their livelihood.

Senator COPELAND. Mr. Godefroy suggested the idea that we should make it specific that when we said "the public", or it was Mr. Lever perhaps, that we should say "consuming public", to make sure that these were not interested persons, and that if they had any interest, it was in the consumer. However, you make your suggestion.

Mr. KALLET. It is not the particular personnel that I am concerned with now; it is the fact that of the 7 members of the committee, 3 representing the public ostensibly at least would be actually volunteer workers. They would not be able to devote much time to the job, even if they were paid a per diem. It would be an encroachment on their normal activities.

The 2 members of the industry, on the other hand, would be provided not only with high pay, but even in the absence of that, with all the kinds of service they could need, by the industry they represent; there would be large staffs, research workers, everything they needed behind them to assure their proper functioning in the committee, and by proper I mean their functioning in the interests of food industries, which I am sure you will admit are usually or at least have been in direct opposition to the interests of the public.

Senator COPELAND. We thought we were using a good deal of finesse in making that particular committee 7 instead of 5 as the public health committee is, by adding 2 members from the Food and Drug Administration.

Mr. KALLET. The trouble is that these 2 members from the industry are going to come there with all kinds of information at their finger tips, they will be well equipped by their lawyers with legal technicalities and objections, and they will actually be able to run the committee.

I object to having any representatives of the industries on any such committee. If any information is needed of a technical nature, the members from the Food and Drug Administration are in a position to get that information, but as it certainly would work out, the members representing the public would be quite helpless alongside of the experts provided by the industries.

I object again to the advisory committees which this bill proposes to set up. Miss Florence Wall, in her comments yesterday, I think, put her fingers on this situation very nicely when she approved of these advisory committees because they would give the industries the opportunity to make their own regulations. That, in practice, is exactly what might happen. At the present time they have lobbyists, their contact men, their liaison officers who are able to bring a great deal of pressure, who are able to make their wishes known in every conceivable way, and they do not need additional representatives right in your functioning organization as this bill provides. They will take care of themselves. You are only making it a little easier for them by providing such advisory committees, and there is a real danger that they would be in the position of making their own regulations.

I object particularly to turning over to a committee or to a trade association representing the advertisers, the control of the advertising, as this bill contemplates.

Senator COPELAND. I fear that the language in connection with that—where does it appear in the bill? I fear that we have not been quite happy in our choice of language there.

Mr. KALLET. Section 704, page 31.

Senator COPELAND. The language is beginning on line 9:

> To aid in securing compliance with the requirements of this Act, the Secretary is further authorized to accept plans for such self-regulation of advertising or trade practices as tend to effectuate the purposes of this Act, et cetera.

If you interpret that to mean that the Secretary is going to turn over, body and breeches, if I may use that term, the whole control of the industry, I do not think that is what we contemplated.

Mr. KALLET. I know you do not contemplate it, Senator, but you have a situation which you mentioned a little while ago, that there is not going to be enough money to enforce this whole act, particularly as set up in this bill. The functions of the Food and Drug Administration are going to be vastly greater than they are now, and properly to control advertising alone, would take far more than their entire budget at present.

Senator COPELAND. Your chief objection to this particular clause that we are now discussing is the word "accept"?

Mr. KALLET. I think that clause should come out altogether. I do not see why the advertisers or any other business interest should be empowered to regulate themselves any more than, as Mr. Mathews suggested, that kidnapers should be permitted to regulate themselves. We have to face the fact that the interests that this bill would control in the aggregate are doing far more damage probably than the entire criminal population of the country, or at least those in the prisons. They are actually killing people and are actually injurying people. Dr. McCormick, of Kentucky, yesterday pointed out that one cancer remedy alone probably was responsible for the deaths of many thousands of women. We are dealing with people who are jeopardizing life.

Senator COPELAND. No; that is not what he said. He said that by the use of that remedy, they kept themselves from the proper medical care they should have.

Mr. KALLET. Don't you think that is the same thing?

Senator COPELAND. I would not think so.

Mr. KALLET. Or equivalent to it, at least?

Senator COPELAND. No. Self-medication is going to go on. I remember the case that he had in mind very well. But that was a long while ago.

Mr. KALLET. There are similar things now. If there were not, there would not be objection to this long list of diseases that you had in the original bill.

In any event, we certainly do object to even their own regulation, and particularly in connection with a matter such as this, which vitally affects health and often life.

As to our concrete proposals, they are embodied in the bill which we presented last year. The first, and I think the most important one that has been mentioned by others at this hearing is that of the licensing of manufacturers of foods, drugs, and cosmetics which may be potentially injurious to health.

As it has been said, there is no more reason why a manufacturer may be absolutely ignorant of medicine or pharmacy and should be able to go with his business, no more reason than a man being able to go into the drug business without having a pharmacist license or being able to become a medical practitioner without a license to practice medicine. It requires a great deal of technical and scientific knowledge to do these things properly, and there is no reason why in your bill you should not require that proof of such knowledge be given to some properly constituted authority.

In connection with that, there is also the possibility of raising money for the enforcement of the law through the license of business. In New York State the dairies are licensed; there are license fees from that. In Pennsylvania ice-cream plants are licensed, bakers are licensed, and funds for the enforcement of the law are obtained from such license fees. There is nothing un-American or nothing contrary to our accepted principles in that. I see no reason why that same method should not be used in connection with this law. As our governmental system is now constituted, the opportunity for tremendous pressure by business interests being what it is, it is probably going to be impossible to give any large increase in the present appropriation. If this bill goes through with this extension to advertising for cosmetics, it is going to mean an adequate amount of funds for the Food and Drug Administration, and these inadequate funds are going to be spread thin over these many activities, and instead of getting better control they will give less control in more fields, and only through such devices as licensing and fees do I think it will be possible to get the funds which will permit adequate control of foods, drugs, and cosmetics.

We feel, also, that the products should be licensed or registered so that we could be sure at first hand that no dangerous product or one that is worthless for any purpose would go on the market.

Senator COPELAND. A manufactured product?

Mr. KALLET. Yes. That also seems a reasonable provision and one which would extend a measure of safeguard to the consumer.

As I mentioned before in connection with advertising, we feel that all claims to be made in advertising of products which affect

health, shall be approved in advance, and that only approved claims be made.

And finally, it seems very important to us that full and complete publicity be given not only for the court decisions growing out of the actions taken by the Food and Drug Administration, but for the bringing of actions for seizures. We constantly read in the papers now of people arrested for doing various things. The reporters of the newspapers do not wait until there is a conviction before they say anything about it. Here there is even more reason why warning should be given to the consuming public at the earliest possible moment when there is a seizure made. It may take a long time for a case to be adjudicated, it may take years for it to get through the courts, and meanwhile the consumer has to be even without the protection of a warning.

Senator COPELAND. I want to call your attention to the reference there to the page regarding publicity—page 50. And on page 51, beginning at line 11, there is this language:

> Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

I do not think that any power has been taken away from the Department to give such publicity as you have in mind where there is a direct invasion of the public health or a threatened invasion.

Mr. KALLET. The power exists now, but it is not exercised, and unless it is specifically provided in this bill that publicity shall be given to seizures and other actions; it won't be done.

Senator COPELAND. Don't you think it is a little unfair, however, where a seizure has been made—I do not mean where there is an invasion of public health or imminent peril to public health, because I would go as far as anybody in that—but where it is a matter of misbranding or technical violation, don't you think that there should be a period between actual publicity and court action, and knowledge gained by the Department?

Mr. KALLET. The difficulty is that when you begin to make exceptions and try to draw a line by which you shall start giving publicity, the line gradually extends until you come back where you started.

Senator COPELAND. But that is the reason this language is there in this bill, to accomplish the very thing you have in mind.

Mr. KALLET. But the trouble is that acts which would repress business are not carried out unless they are specifically required, and even then they are not always done, but left as it is in this loose language, the publicity would be just about the same as it is now, for the results of court actions is often years after the case originated.

Senator COPELAND. You do not give much credit to these chaps over here at the newspaper table.

Mr. KALLET. When the newspapermen have tried to get information about such cases in the past, it has been denied them by the Food and Drug Administration.

Senator COPELAND. I did not suppose there was anything a newspaperman could not get. However, we have made a note of your criticism.

Mr. KALLET. I could go on for some hours talking about the things that I think are wrong with the bill, but it would not serve any purpose now.

I do not like the bill. I think from start to finish it does not afford protection to the consumer, and I would like to propose at this time that in deference to the consuming public, a new start be made, that is, that instead of having a bill just written, you start with an investigation of these industries. I propose that you introduce in the Senate a resolution calling for an investigation of the food, drug, and cosmetic industries as a basis for a bill. We are not anywhere near ready yet to start with our legislation. We have tried to write a bill which we thought would properly protect the public, but we cannot write the kind of a bill which is the right kind of bill. It requires a commission of experts from many fields who will spend a great deal of time and effort to get a proper basis for such a measure as this.

Senator COPELAND. Is it better for us to leave conditions as they are, with the recognized defects in the present law and then wait until such an investigation has been made?

Mr. KALLET. I think it would be far better than passing the bill as it stands now. That, in my opinion, will add very little to the protection of the public. That is all I have to say.

Senator COPELAND. Thank you.

Senator GIBSON. Is there any other person on the list of witnesses who has not been called?

(No response.)

Senator GIBSON. If not, the committee extends its appreciation of your cooperation, and the hearings are closed.

Senator COPELAND. Mr. Chairman, we would like to have if possible the briefs in by Monday night. I think all the briefs have been filed, but if there are exceptions please get them to us by Monday if you can.

(Whereupon at 2:15 p. m., the hearings were closed.)

STATEMENT OF DAVID E. GOULD, OF GOULD-NEGATIVE-ION-CO., BOSTON, MASS., IN RE FEDERAL FOOD AND DRUG ACT

THE AIR A DRUG; TO LAUGH OR CRY, THAT IS THE QUESTION

Argument against so much of the bills pending for enactment as provides "that all devices intended to be used for the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of either man or animals."

This definition as applied to devices will apply to all forms of physical therapy apparatus now in use, as well as to any that may be found to be helpful in the cure or mitigation of disease in the future.

It is so all inclusive, that it will apply to any use of the air, of oxygen which is taken from the air, and every method of physiotherapy which has to do with the air we breathe.

If you pass this or any similar measure to include air, you will be the laughing stock of the Nation. The newspapers and magazines will see to what absurd extremes the administratiton will go in the name of reform, and they will bring the blush of shame to those who perpetrate this outrage.

Probably at no time have men thought with their emotions and lived on the level of their prejudices more than they are doing now. This affords the opportunity for the medical profession to take entire control of all methods of healing. It sounds the death knell of all progress in the aid of suffering humanity.

Scientists who have done so much toward developing modern methods, often with so much obstruction from the medical profession, will find no incentive to devote their lives to progress if their discoveries can be aborted by such legislation.

Sir Arthur Salter, international economist, has said "We are, if we could grapple with our fate, the most fortunate of the generations of men. In a single lifetime science has given us more power over nature, and extended further the range of vision of the exploring mind, than in all recorded history."

Scientists and scientifically minded doctors are the ones who can claim credit for any advance in medical practice, and no one else. And scientists have been saying their discoveries would revolutionize medical practice, and I say only over the dead bodies of the medical profession will this be done.

Those who vote for this bill may be well meaning, though woefully ignorant of the facts. Few of the public, including Members of Congress, have knowledge of the long-existing feud between the doctors who practice with drugs, and those who practice by physical therapy.

So bitter has this feud become the American Medical Association has felt obliged to severely censure the drug branch of the profession. I quote from an article in their Journal, June 2, 1934, issue. The article is entitled, "The teaching of Physical Therapy to Undergraduate Medical Students." "No matter how vigorously the medical profession may deny utilitarian objectives in medicine, the physician, after all, to his patients in general is a healer, and his duty to the individual who is ill involves the use and application of all therapeutical measures conducive to the restoration of that patient to health. There is, we believe, a growing consciousness on the part of the medical profession of the great value of the numerous procedures known as 'physical therapy.'" There is much more in the article along similar lines well worth reading if you want to get a clear picture of the struggle going on between the two branches of the profession.

No doubt realizing how difficult it will be to change the views of the drug doctors against their financial interest, again to A. M. A. in their Journal, December 22, 1934, issue, take up the cudgel again in behalf of physical therapy. The article is entitled, "Education in Physiotherapy", see page 1944.

Are you "babes in toyland?" Do you think you can legislate to change human nature Will doctors who can treat many patients in a day by writing prescriptions for drugs readily adopt a different method of practice which will materially reduce their income? Will the A. M. A. have any better success with such a handicap?

Practice with physical therapy devices requires treatments usually from 15 minutes to 1 hour. The Gould negative ion process, in whose behalf I speak, takes from 1 to 2 hours, depending on the nature of the disease. Against this, the writing of a prescription may take only a few minutes. What chance do you think we have of gaining a fair hearing before a profession, more than 90 percent of whom are hostile to physical therapy practice in any form. Is there any question about who will be appointed to the board to advise the Secretary of Agriculture? Of course, they will be physicians, and they will stand by their profession, and what the majority of them want; regardless of suffering humanity who will have no chance of a hearing in their own behalf.

The medical profession are fast losing the confidence of the public, and they know it only too well, it is a matter of secret discussion where doctors meet. How necessary, therefore, to cinch their hold on the public at this time, when anything under the name of reform is the magic word for legislation.

Last spring the Philadelphia Medical Society invited the sociologists to a conference. What was expected to be a love feast turned out to be a free-for-all fight. The sociologists accused the doctors of refusing to adopt new methods of practice, and of many sins of commission and omission. Michael Davis, director of the Rosenwald Fund, said, "The American public are likely to become impatient with those who do nothing to aid experimentation." The newspapers headlined this, so the society hurriedly called a meeting 3 days later and issued conciliatory statements to the public. It also brought forth the statement from Dr. Morris Fishbein, then president of the A. M. A., that the A. M. A. had never opposed honest experimentation.

Take our case, after 4 years of work by scientists we have developed a process which includes the negative ions in combination with an ozone produced by ionization. We induct the negative ions into the body by the method described by American scientists. See textbook by Prof. James Arnold Crowther, third edition, 1922.

The negative ions as a means of healing was developed by Prof. F. Dessauer, of the University of Frankfort, Germany, who spent 10 years with his coworkers in experimental work before he announced his discovery to the world. The Dessauer process has been in use in the Beth Israel Hospital, New York, and the University of Wisconsin for the past 2 years. It has been in use in parts of Europe for the past 4 years, in leading hospitals and among leading physicians there, and they report that they are treating diseases successfully that our physicians have no remedy for.

We have had similar success with our process in treating cases the medical profession cannot help. We have advertised in Boston newspapers, and used the radio in describing the results obtained, and have invited the Massachusetts Medical Society to investigate the cases and report their findings; that was 8 weeks ago, and we have heard nothing from them. This is considered as commercial by the profession; their so-called "ethics" is against advertising except direct to them through their medical journals. No one must tell the public anything about any new and revolutionary method of treating disease; if for pecuniary reasons they do not see fit to adopt the new method, they are safe from interference, and it is only too bad for the afflicted.

For those innocent souls who will ask why don't you go to the A. M. A. for approval of your device, my answer is, the A. M. A. will not investigate what we have accomplished, our records will have no value to them. The first thing they will say is you must take control cases for treatment by drugs and by your physical therapy device. Control cases mean, two cases of the same disease in precisely the same state of development; you may say this is impossible to all practical purposes, but that will make no difference to the A. M. A. Under the most favorable conditions the association will hold us up for 1 or more years.

We have a better idea than that; if we are let alone and protected from blackmail suits, the medical profession will be obliged to recognize our process or lose their practice on cases they have no remedy for, and which our process will help. Already the news of our work is spreading in Boston and vicinity; even doctors who can do nothing for themselves have taken the treatment, and an occasional broad-minded doctor is sending patients here for treatment.

Daily we hear the cry, "they have taken our money and have done nothing for us." We turn patients away unless we are satisfied we can help them; this is a daily occurrence. We will not treat people just to get their money—isn't that the best kind of a new deal?

I suppose you are all more or less familiar with the struggle with the medical profession to secure the adoption of vaccine as a protection from small-pox.

See A. M. A. Journal, December 1, 1934, issue, for report on results from the use of oxygen.

It is the same old story, the "heresies of today are the accepted practices of tomorrow." No future civilization or culture worth the travail of its birth can carry on to the heights of possible attainment without the full exercise of our freedom. Yet no freedom is an end in itself: it must expire if it fails to serve.

Brief of William Y. Preyer on S. 5, Committee Print No. 3

My name is William Y. Preyer. I am filing this brief on behalf of, and as chairman of, the advisory committee on advertising of the Proprietary Association, the Vick Chemical Co., of which I am first vice president, and for myself as a member of the industry affected.

I should like to point out that the advisory committee on advertising represents the first movement in any industry, so far as I know, to control the advertising of an industry through self-regulation.

We offer counsel, without charge or obligation, to all advertisers in the drug field as to how they may make their advertising copy free from objection. We have given service to a large number of advertisers, with the aid of qualified consultants in the fields of medicine and pharmacy. We have made many recommendations and our recommendations have met with practically complete acceptance from those whom we have served.

This experience has given us some basis for an opinion as to the most effective way of getting advertisers to make advisable changes in their advertising copy. It has likewise given us the basis for an opinion as to the most effective way in which the Government can get advertisers to make desirable changes in their advertising copy.

When our committee set up its procedure, we tried to establish a method that would work. Likewise, in thinking about legislation in this field we should like to see a procedure established that will work. We believe we can get the quickest results through a fair and reasonable procedure, and we likewise believe that the Government can get the quicket results, without resistance and delay, through a procedure which advertisers recognize as fair and reasonable.

We want to make it clear that this committee favors the passage of food and drug legislation at this session of Congress. We favor it as support for the work of our committee.

In considering this legislation, which is to regulate the advertising of the drug industry, we feel that recognition should be given to the part which may be played by self-regulation within that industry.

We likewise feel that such self-regulation can best be carried on in cooperation with the Federal Trade Commission, and consequently we favor the retention by that body of jurisdiction over advertising and the strengthening of its powers to deal with false advertising.

The Federal Trade Commission has the necessary experience in handling advertising, having already dealt with many thousands of cases. It has available the technical counsel of the Bureau of Public Health, the Bureau of Standards, and of the Food and Drug Administration. Its procedure gives opportunity for discussion with the advertiser and for the handling of cases by stipulation.

We want a workable law. We do not want a law that will invite invasion and delay because it is felt to be unreasonable. For this reason we do not favor punishing an advertiser for phrases in an advertisement by means of multiple seizure and criminal court action.

As a workable law, one which will get results because it will be recognized as fair and reasonable, we favor provision for Federal Trade Commission proceedings with recourse to action in the civil courts. We believe in strengthening the powers of the Federal Trade Commission to deal with false advertising, and we believe in providing the power of injunction to stop serious cases of false advertising. This is the procedure recommended in the Mead bill.

Gentlemen, all we are interested in is securing a fair, reasonable procedure for dealing with advertising according to American traditions. We think it is according to American traditions to establish a procedure under which an advertiser may, in the first instance, discuss his problem, understand what objections are made to it, and agree to desist from objectionable statements. Then in the second instance, he should have a formal hearing. In the final instance, he should have recourse to the civil courts. We think it is bureaucratic and un-American to set up a procedure under which a single Government bureau may make the law by regulations, and enforce it by multiple seizure, against which there is no practical possibility of defense, no opportunity for reasonable discussion, with no final recourse except to criminal court proceedings. We object to this procedure; we do not think it is fair to industry, nor will it give any greater protection to the public. Advertising should be retained by the Federal Trade Commission.

STATEMENT OF W. G. CAMPBELL, CHIEF, FOOD AND DRUG ADMINISTRATION

An extended discussion by me of the provisions of S. 5 is unnecessary. S. 2800, a measure which contained a number of the sections of S. 5 in identical or similar form, was discussed at length. The changes found in S. 5 are in all instances for obvious reasons and operate to strengthen the bill. A number of suggested amendments offered in the course of this hearing deserve critical consideration. In commenting on them I shall also, for purposes of clarification at least, advance certain suggestions by way of amendments with a brief statement of the reasons therefor.

Definitions.—There is a universal recognition that the definition of the term "drug" in the third subdivision is inclusive. This fact was admitted at the hearing on S. 1944. To provide for jurisdiction over the innumerable devices to which therapeutic virtues are ascribed, it will be necessary either to operate under a definition of this character, as incongruous as it is, or to set up, as proposed by one witness, an independent paragraph relating to therapeutic devices

In the definition of medical opinion, it is suggested that the word "jurisdiction" and all that follows in lines 22 and 23 (p. 3) be stricken. In lieu thereof insert "State or Territory where any drug to which such opinion relates is held for sale or otherwise." As the definition now stands, it would be possible only through the medium of seizure action to protect consumers in States where the medical opinion relied upon for support of the claims on the label had not been legalized. As an illustration, a manufacturer operating in the only State in the Union which had legalized the practice of some fantastic cult of the healing art, could ship his products throughout the country without interference by criminal prosecution or injunction. The change will permit shipment of such products into those States only where the medical viewpoint exemplified by such articles is legalized.

Adulterated food.—Some concern has been expressed about the significance of the word "dangerous" as used in the definition of adulteration of food, section 301 (a) (1). There is a possibility that this concern is due to a misunderstanding of the purpose of subparagraph (1). It relates primarily to foods naturally containing poisonous constituents. The following subparagraph (2) is the authorization upon which reliance is placed in suppressing traffic in food products to which poisonous ingredients have been added. The first subparagraph is an extension of authority to interfere with foods that have been prepared under Nature's formula. The existing law does not contain a comparable provision for the regulation of domestic commerce. In 1902 in the House committee hearings on the Mann-Corliss and Hepburn bills, Dr. Wiley opposed the former on the ground that one of its sections declared a food product to be adulterated if it contained any substance which would render it deleterious to health. He endorsed the Hepburn measure because "it contains no provision which prohibits the transportation of an article of food which contains an injurious substance as a part of its natural composition." Dr. Wiley asserted that if the Mann-Corliss bill were enacted it would outlaw tea and coffee. To these could be added other natural foods which have constituent elements that might be injurious, such as rhubarb, which contains oxalic acid, and cocoa, which contains theobromine. The word "dangerous" was selected deliberately to avoid interference with traffic in coffee, tea, cocoa, and the like, but to provide authority to suppress the sale of poisonous mushrooms and some dangerous sea foods, like west-coast mussels, which are particularly toxic at certain periods of the year.

In paragraph (d), line 18, the insertion of the word "harmless" before "flavoring" is suggested, so that that portion of the paragraph will read "harmless coloring, harmless flavoring", etc.

Misbranded food, section 302.—Two substitute paragraphs have been offered for paragraph (k) of this section. One of these would legalize the use without declaration of artificial color in ice cream. The other would legalize likewise the use without declaration of artificial color in all manufactured food which is not in imitation of a natural food. Neither of these meets the purpose for which this paragraph was designed. The bill specifically forbids the use of color where it operates to conceal damage or inferiority or to create a deceptive appearance. Assuming that the use of artificial colors is without objection on any of these grounds, the consumer can insist upon his right to information on this score, and it was with that idea that the paragraph was inserted. It merely promotes fair dealing. What objection can there be to a declaration of the presence of artificial color where artificial color may be used without otherwise violating the law?

Definitions and standards for food, section 303.—The proviso of this section states that no standard of quality shall be established for any fresh natural food. This was for the purpose of exempting fresh fruits and vegetables from the operation of this section because standards of quality now exist for such products under the terms of the Fruit Products Inspection Act enforced by the Bureau of Agricultural Economics and State organizations. The question arises, however, about the probability of the language including more than fresh fruits and vegetables. Maple sirup and maple sugar manufacturers of Vermont are anxious to have a standard of quality suitable for that product. It is suggested that the language be changed to read: "*Provided*, That no standard of quality shall be established for fresh fruits and fresh vegetables." If this amendment is accepted there should be a corresponding change in the wording of section 302, paragraph (1).

Emergency permit control, section 305.—In paragraph (a), line 17, immediately following the word "thereof" it is suggested that there be added the

words "in any locality." The purpose of this addition is to make definite the meaning of the paragraph. As modified, the secretary will be empowered to require permits only in that location of the country where this extreme measure of control is necessary. Unmodified, it is not clear whether he could restrict his action to the offending locality or whether he would be required to insist upon permits being secured by all manufacturers throughout the country producing the class of food to which the regulation applied.

I recommend also that all of this paragraph beginning with the word "requiring" in line 24 be stricken and that the following be substituted: "thereafter no manufacturer, processor, or packer of such class of articles shall introduce into interstate commerce any such food unless he holds an unsuspended valid permit issued by the secretary as provided by the regulations." The purpose of this is to have the act directly express the prohibition rather than leave that to the secretary's regulation.

Adulterated drugs, section 401.—Objections have been recorded to the definition of adulterated drugs in paragraph (a) (1). The basis of these objections seems to be largely the offense which it involves against standards of accurate English. It is asserted that since the danger to health is occasioned by the character of directions for use appearing either on the labeling or in the advertising of the product, the offense should more appropriately be catalogued as one of misbranding instead of adulteration. If that were all that is involved in this proposal no comment would be offered here. It is immaterial to the public whether suppression of the offense occurs under an allegation of adulteration or one of misbranding. It is the restriction simultaneously recommended to seizure of misbranded foods, drugs, and cosmetics which inspires opposition to the proposal. The inclusion of this definition grew out of recognition by the Government of its inability under the terms of the present law to protect consumers against such drugs as are per se harmful when used as directed. The language relates only to products of this character. The definition does not apply to innocuous drugs making extravagant curative claims on the label or in the advertising. The grave nature of the offense warrants its present classification. There is no incongruity in the retention of this language in the section defining adulteration. There is nothing to be gained by transferring it to the section defining misbranding.

The only portion of the remaining provisions of this section to which much comment was directed is the so-called "variation clause" in paragraph (b). This paragraph relates to official drug products, that is, those listed in the pharmacopoeias and National Formulary. Like existing law, it regards a drug product purporting to be a pharmacopoeial or National Formulary article as adulterated if it differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth therein. The bill also provides, as does existing law, for variation from such requirements upon an indication of that fact on the label. Earnest recommendations were made for the deletion of this authorization for variation. The force and logic of such recommendations cannot be ignored. The argument is based upon the postulate that standards are of no value unless observed and that an authorized sweeping variation from the requirements is tantamount to a repeal. What properties of a drug are connoted by standards of strength, quality, and purity, and what scope in variation from these standards is allowed by existing law, has not been determined with finality by the courts. In recognition of the fact that the active ingredients of crude drugs will vary not only in different sections of the world in which produced but will vary in the same section from season to season, some provision for the marketing of drugs in the crude state should be made which will not require them to conform rigidly to the standards set forth in the pharmacopoeia when they are to be used for manufacturing purposes and the finished products meet in all respects the standard of potency and purity prescribed in the pharmacopoeia. In such instances the variation of strength, quality, and purity from the legal standards does not contemplate or authorize a variation in identity. Whether or not variations no sympathetic consideration of the proposition that such variations also include standards of identity. There can be no excuse for legislation to permit the sale of one drug product under the name of another. It is not only inconsistent with the general purpose and spirit of this bill but thoroughly contradictory and repugnant to both the terms and the object of it; likewise of the the present law.

Misbranded drugs, section 402.—It has been recommended that the phrase "in every particular" in paragraph (a), line 13, be deleted and that the word

"supported" be substituted for "sustained." The only plausible reason advanced for the elimination of the phrase "in every particular" is that it is redundant. Its omission does not, in my opinion, diminish the requirements of the paragraph. If a label or advertising statement is true, it is true in every particular; and conversely the falsity of any part of such label or statement would render the label or statement false. Perhaps, therefor, the standard of truthful labeling and advertising practices required by this paragraph will in no wise be lowered by the elimination of this phrase, and the protection of the public will be underwritten as thoroughly by its deletion as by its retention. The question arises, however, whether the continuation of the phrase might not serve a useful purpose to manufacturers. Its presence emphasizes the fact that deviation from the truth in the preparation of labels and advertising statements is permitted in no particular. As a signpost to those engaged in the service of formulating labels and preparing advertising statements, it points definitely the road to compliance with this paragraph. To that extent, in my judgment, it serves a good purpose.

If the suggestion that the word "sustained" be supplanted by the word "supported" is with the idea that scientific facts and medical opinion will be required in smaller degree as an indorsement of therapeutic labeling or advertising claims, there is ground for vigorous objection to this proposal. It has been brought out in the testimony of one witness that the dictionary definitions of these words offer no satisfactory basis of a comparison of them from the standpoint of their respective requirements as used in this paragraph. Believing that producers and distributors of drug products, in furtherance of the practice of self-medication, should observe the most exacting requirements for conservative rather than extravagant curative claims, I urge the retention of the word "sustained" if indeed it does impose in this direction greater care and greater discrimination by the manufacturer.

Suggestion has been made that paragraph (f) be deleted. This proposal is advanced in the understanding that paragraph 401 (a) (1) makes paragraph (f) unnecessary; 401 (a) (1) deals with products which are of a toxic or poisonous character and with directions for their use. Paragraph (f) relates more to the precautions which should be expressed against the misuse of potent drugs. This is particularly true in the sale of powerful sedative drugs, particularly those which affect the heart. The consumer will ordinary be without knowledge of the consequence of a too frequently repeated use and might be induced, in fact frequently is induced, through securing partial relief from the first dose, to repeat or increase the dose, to his very definite injury. A precautionary statement against misuse in this manner should be carried in a conspicuous portion of the labeling of such products.

Likewise the suggestion was made to delete paragraph (g). The very definite purpose of this paragraph is recognized when consideration is given to its application to a product like bichloride of mercury tablets. It should be retained.

Representatives of antisceptic and germicide manufacturers are again opposed to that portion of this bill relating to these products. I am aware of only one proposal of a substitute for any portion of the language of paragraphs (j) and (k). However, the author of this, in common with all others speaking critically, favored elimination of these paragraphs. A solution of this question by its effacement is predicated on the declaration that other provisions of the bill are sufficient for adequate control of antiseptic and germicidal products. This conclusion cannot be justified by a careful analysis of the bill. Products sold as antiseptics have been found to represent almost every degree of variation in germicidal properties from that of a negligible character to an efficient germicide.

The important medicinal function which such products are to perform—their value in the prevention of infections which may develop into serious pathological conditions—emphasize the necessity for standardization. All that is sought by this language, which has admittedly a vagueness to the nontechnical reader, is that (1) such products have germicidal properties, (2) that the label state its use and method of application, and (3) the duration of time through which such use should occur to effect its purpose. The standard proposed is a chemical standard, susceptible of less variation than would be encountered in bacteriological standards. Certainly there can be no quarrel with the purpose of these paragraphs. Unquestionably proper protection of the public through the regulation of traffic in such products requires their retention. On

previous occasions I have said that our present regulation of such products was more through the medium of persuasion than by the exercise of power. In asking for a statutory requirement to forbid the sale of antiseptics with no greater germicidal properties than that possessed by cold water and to require that such articles conform to the proven scientific conception of an antiseptic or germicide, nothing more is sought than a legislative confirmation of the existing administrative attitude, which is unqualifiedly supported by reputable manufacturers.

Adulterated cosmetics, section 501.—Two or more witnesses have urged an additional provision to this section requiring that allowances be made for allergic tendencies. A consideration of the language employed in defining the adulteration of a cosmetic under paragraph (a) discloses the fact that those products only are considered as adulterated which contain poisonous and deleterious substances and then only when such substances are present in that quantity which may render the product injurious. This would not prevent the marketing of a talcum powder, or a face cream, or any other cosmetic which did not contain poisonous ingredients, even though such cosmetics might contain ingredients to which a certain class of unfortunate people were allergic. The bill will not restrict the production and sale of cosmetics which are free from poisonous ingredients, even though some people may be allergic to such nonpoisonous substances. To request, however, allowances for poisonous ingredients on the ground of allergy is not, in our opinion, justified, and provision to that effect should not be incorporated in the measure. Otherwise many shocking abuses will be perpetuated.

False advertisement, section 601 (a).—The comments offered on 402 (a) are applicable to this section.

Public health and food standards committees, section 703.—Paragraph (c), in line 14 and following, authorizes the Secretary, after hearings, to formulate and promulgate regulations. The language used is unusually broad. In order to express the legislative intent and in order to restrict the regulation-making power of the Secretary definitely to the expressed purposes of the Congress, and thereby guarantee that the legislative program as expressed in the provisions of this bill will be definitely observed, it is suggested that the sentence beginning with "After", in line 14 and concluding with "committee" in line 18, be substituted by the following: "After such hearing the Secretary is authorized to formulate and promulgate such regulation as he shall find to be necessary to effectuate the purposes of such provision, but no such regulation shall be promulgated without the approval of a majority of the members of the committee." To effect conformity of other wording in this paragraph to the suggested change, it will be necessary to substitute "any" for "the" in line 7, and to make the word "provisions" singular.

Examinations and investigations, section 705.—An amendment to this section was introduced by Mr. Charles Wesley Dunn requiring that a representative part of all samples of foods, drugs, and cosmetics collected for analysis be delivered to the interested producer or vendor. The amendment also requires that, upon application, information concerning methods of analyses used and tolerances recognized be disclosed. This amendment on its face has the appearance of fairness. There would seem to be slight, if any, objection to its provisions. In fact there would be no objection whatever to a fulfillment of this requirement if all producers and distributors of food, drug, and cosmetic products were honest. It was the protection of the interest of manufacturers of this class undoubtedly which Mr. Dunn had in mind. Unfortunately, however, there is a percentage of producers and vendors who cannot be placed in this category. To accord to them the consideration indicated by this amendment would be to guarantee in many instances the defeat of the Government in such litigation as might develop. To make it compulsory upon the Government to comply with this requirement is establishing a statutory defense inconsistent with the ends of justice. Distribution of a great many products, particularly in mail-order business, is in quantities so small that the entire sample will be required for governmental analysis. In such circumstances a subdivision could not be effected and no prosecution could be developed. The attention of the committee is directed to existing regulations. Regulation 3, paragraph (c), of the regulations for the enforcement of the food and drugs act provides for the delivery, upon request and, if available, of a subdivision of the sample to interested parties. This question is one for proper treatment by regulation rather than by legislation.

Factory inspection, section 707.—The criticism directed at this paragraph is on the severity of the penalty provided. There is no comparable requirement in the present Food and Drugs Act. Experience has demonstrated time and again the importance of some legislative authorization for an inspection of equipment and material used in manufacturing plants, but more particularly the finished product as held both prior and subsequent to interstate delivery. The severity of the penalty provided in S. 5 is recognized. However, severe as it is, it is definitely tied up with interstate transactions in order to avoid the pitfalls of unconstitutionality which seem to characterize the amendments which have been offered to this provision. Clearly Congress cannot confer upon a Federal agency the power of control over manufacturing operations within a State. That is exactly what is done by amendments providing injunctive remedies against refusal to permit inspection. To avoid the obvious unconstitutionality of such provisions, paragraph (*b*) of this section authorizes the courts to deny the channels of interstate commerce to the manufacturer refusing to permit inspection. The only alternative to an injunction against interstate shipment is the imposition of penalties in the nature of fines for interstate shipment occurring after refusal and before permission is finally given. In order that this paragraph may prevail in the face of the attack which will be launched on the ground of unconstitutionality and in order that at the same time the objection which has been registered against the severity of penalty may be overcome, I propose the following substitute for paragraph (*b*):

(*b*) In order to keep the channels of interstate commerce free from adulterated and misbranded articles of food, drug, and cosmetic so as adequately to protect public health and welfare, the introduction or causing to be introduced into interstate commerce, or delivery or causing of delivery after receipt in interstate commerce, of any food, drug, or cosmetic from any factory, warehouse, establishment, or vehicle, designated in paragraph (*a*) of this section is hereby prohibited if the owner, operator, or custodian thereof has, after reasonable request, denied permission to officers or employees duly designated by the Secretary to make the inspection authorized by such paragraph; and any person who introduces or causes to be introduced into interstate commerce, or delivers or causes to be delivered after receipt in interstate commerce, any food, drug, or cosmetic from any such factory, warehouse, establishment, or vehicle after the owner, operator, or custodian thereof has, after reasonable request, so denied permission to make such inspection shall be guilty of a misdemeanor; and for each such introduction or causing to be introduced, or such delivery or causing of delivery, after such denial and until such permission is granted, such person shall be liable to a fine of not more than $50.

Seizure, section 711.—An amendment was offered to paragraph (*a*), the purport and effect of which is not altogether clear. That amendment authorizes attachment of adulterated and misbranded goods by libel "if it appears to the court that such proceeding is necessary to effectuate the purposes of the act." The present statute authorizes the action which paragraph (*a*) in unmodified form outlines. Like this section of the bill the law also directs that proceedings shall conform, as nearly as may be, to the proceedings in admiralty. The filing of a libel and the subsequent issuance of a monition involve specifically or by implication a conclusion on the part of the court that such action is requisite for putting into effect the purposes of the act. To feature that requirement by the addition of the language suggested is easily capable of being construed as compelling to court to make a determination on the merit of the case before authorizing seizure. This would involve a review of all the facts, necessitating the appearance of Government witnesses and perhaps witnesses for the claimant, resulting in all instances in such delay that efforts at procedure in this manner would avail the public no protection whatever. Certainly an acceptance by the committee of this proposed amendment will operate to weaken the protection afforded by the present law.

Another amendment suggested to paragraph (*e*) of this section requires that in cases of multiple seizure one such seizure shall occur within the district where the person whose name appears on the label has his principal place of business, provided the article is available for seizure therein. This proposal will constitute an unfortunate restriction on the consumer protection for which such proceedings are employed. It is by this method that adulterated products which may be dangerous to health or which are filthy, putrid, and decomposed, or involve cheats upon the public, are removed from the channels of commerce. Multiple seizures to which the amendment refers are reported to only when the character of the offense is reprehensible. In such circumstances that

unctuous consideration of the manufacturer which this amendment would bring about is foreign to the purposes of the section. Its observance would jeopardize the power for the protection of the public which is contemplated by this section and which exists at the present time. I earnestly hope the committee will not in any way diminish the power that we now have for the protection of the public by this type of legal action.

Injunction proceedings, section 712.—The language in paragraph (*a*), subparagraph (2), is involved. This in part results from the additions indicated by the italicized words. I appreciate the purpose which the change was intended to effect and am wholly sympathetic with it. I suggest for the sake of clarification, however, that the phrase beginning in line 15, "at subsequent intervals of time and within the advertiser's control of repetition", be stricken and that a new sentence be added at the conclusion of paragraph (*b*) reading: "No person shall be deemed to have violated an injunction, issued pursuant to this section, by reason of the dissemination, subsequent to such injunction, of the false advertisement which was the basis of injunction, if such dissemination was beyond the control of such person." The purpose of this paragraph as it is now and as it may be modified by the amendments herewith proposed is to exempt advertisers from contempt proceedings in circumstances which are beyond the advertiser's control. For example, the preparation and set-up of periodicals take place considerably in advance of their distribution. It is beyond the power of the advertiser to recall an advertisement which appears in such periodical even though an injunction may have issued prior to the date of its appearance but subsequent to the date of the locking of the forms of the magazine.

Imports and exports, section 714.—In paragraph (*a*), line 8, it was suggested that the word "manufacturer" be substituted for "importer." The effect of this change is obvious. It would authorize the importation of products concerning which false advertising had been disseminated by the importer bringing such products into the country. This is manifestly contrary to public interest and welfare. The change was urged on the assumption that the offense of one importer would deny importations to other importers of the same commodity. This very definitely is not the purpose or effect of the language. The decision at the port in connection with each individual entry will be based upon the behavior of the importer involved. The use of the word "consignee" in line 3 justifies this conclusion. This interpretation works no interference of delivery to innocent importers and authorizes only detention of particular importations where the importer thereof has disseminated false advertising.

Amended title.—Obviously the phrase "and for other purposes" should be added at the conclusion of the title of the act.

Delegation of authority to make regulations.—The most popular criticism directed at this bill is that it confers unusual and unnecessary authority upon the administrative officer. It is asserted that it is a mere skeleton of legislation with accompanying warrant to the Secretary to fill in its needed provisions. A probable explanation of the biggest proportion, if not all, of this criticism is that it is the outgrowth of a habit acquired from commenting on S. 1944. To that measure the criticism in measurable degree was merited. Certainly a careful analysis of S. 5 reveals the irrelevancy of these critical observations. It is extremely difficult, if not impossible, to formulate a legislative measure which will provide for adequate protection of the consuming public in the regulation of a subject as complex and varied as production and traffic in foods, drugs, and cosmetics. It is necessary, after a clear indication of the legislative purpose, to delegate to the executive branch the task of fact-finding as a preliminary to the formulation of regulations for the purpose of giving effect to the expressed legislative intent.

Let us consider both the subject matter and the provisions involving a delegation of power to the administrative official. Approached from a subject-matter standpoint, we find that authority is delegated after appropriate investigations which will result in the determination of pertinent facts to establish, by regulation, tolerances in food products for added poisonous and deleterious ingredients; certificates of coal-tar dyes for use in food, drugs, and cosmetics; standards of identity and a standard of quality and fill of container for food; factory permit control for food; methods of assay for U. S. P. drugs; deteriorated drugs; warning declaration on narcotic and hypnotic drugs; specific precautionary labeling of both foods and drugs where necessary for the protection of children, invalids, and pathological cases; extension of the list of diseases, reference to which is forbidden in advertising. The following instances of delegation of power occurring in the bill are to be found also in existing law: Power to determine and promulgate standards of quality and fill of container for canned foods; general administrative regulations, and, jointly with the Secretary of Treasury, the prumulgation of regulations for the control of imports; the formulation of regulations for administration of the sea-food amendment. The remaining instances of delegated power refer to the exemption of manufacturers from the observance of certain provisions of the bill. Similar authority in some respects is conferred by the present law, such as the determination of tolerances and the exemption of small containers from the requirements of the net weight provision.

Commenting generally upon the particular features of the bill by which this delegation of power is conferred, it is interesting to note that because of the structure of the measure it is necessary in creating the authority for the certification of coal-tar dyes and in the prohibition of the use of uncertified dyes in foods, drugs, and cosmetics, to deal with this subject in six different sections of the bill. The extent to which the impression prevails that this measure is unique in conferring unlimited authority upon administrative officials may be due in a large degree to the frequency with which some phase of the matter is dealt with in the various paragraphs as illustrated by this reference. Continuing the comment on this topic, there certainly can be no objection by manufacturers or others to the incorporation of a provision which permits the certification of coal-tar dyes. In fact, such certification obtains now. It has existed throughout the life of the law. Authorizing a continuation of this practice is merely a legislative confirmation of an administrative procedure inaugurated first, as a protective measure to the consumer, and, second, as a helpful service to the industry. Prohibition against the use of uncertified coal-tar dyes is not effected through regulation but is a feature of the bill itself.

Let us consider briefly the extension of power to formulate definitions and standards of identity for food products. At present there are no legal definitions and standards of identity for foods with the single exception of butter. The legislative standard for that product resulted from a vigorous campaign for it by butter manufacturers. Prior to the passage of the measure amending the Food and Drugs Act by requiring that butter contain not less than 80 percent fat, the condition was chaotic. Butter was produced and sold which varied from 75 to 85 percent fat. In the absence of power to standardize its production, the public was victimized not only, but the unbridled competitive situation was rapidly bringing about a condition of trade demoralization. Since the establishment of the legislative standard, enforcement operations have been simplified, manufacturing practices have been standardized, and, most important of all, the public has been effectively protected.

The necessity for standards of identity for food products is an economic one. Satisfactory enforcement of the food provisions of the existing law or of this bill cannot occur unless legal food standards are established. To the consumer and to the enforcing agency it is immaterial whether these standards are provided through legislative or through executive channels. There is a definite preference by food producers for the latter method because of its greater flexibility and the readiness with which new conditions and new developments could be met and dealt with. Food manufacturers are not objecting to the provisions of the bill which authorize, by regulation, the formulation and promulgation of standards of identity for food products. Their support of this provision is the outgrowth of an extended experience with advisory and therefore unenforceable standards only. To both the consumer and the trade, few food provisions transcend in importance those providing for standards of identity.

A feature of S. 5, which did not appear in S. 1944, providing for food standards and health committees, is a guaranty against arbitrary or bureaucratic action by the Secretary. In their respective fields these committees have a veto power on the proposals of the Secretary. Their appointment by the President presupposes the selection of persons who are competent and fair-minded.

If it is impossible—and that cannot be gainsaid—for the Congress to address itself to the enactment of measures which would set up standards for food products with that particularity, precision, and detail required in the determination of standards of identity for the various items of food, what more equitable or proper formula for the determination of such standards could be devised than that set forth in this measure?

As an indication of the seriousness with which criticism of an extension of power to deal with this subject should be considered, may I point out that most of the objections originate with the packaged medicine phase of the drug industry. Perhaps the ethical element of this group will be affected by the regulation-making power of the Secretary in a smaller degree than any other element of food and drug manufacturers. It is true, as observed by one witness in a dispassionate consideration of the provisions for the delegation of authority to administrative officials, that they are of an unusually temperate character. This conclusion is definitely confirmed by a consideration of the large number of Federal statutes by which power in varying degrees is conferred upon administrative officials. In no instance does any one of the various authorizations in this bill confer upon the Secretary a degree of authority which transcends that conferred by the existing law. The power under the McNary-Mapes amendment to the existing Food and Drugs Act to formulate standards of quality and fill of container for canned foods is, in the degree of the power exercised with finality by the Secretary, greater than that conferred by any of the provisions of this bill. That it will be impossible to enact satisfactory legislation for the regulation of traffic in foods, drugs, and cosmetics without providing for the exercise of delegated authority, and that such extension of power is not unusual and irregular but indeed proper and necessary, is supported by the conclusions of the Supreme Court as expressed in *Union Bridge Co.* v. *United States* (204 U. S. 387). In that decision the Court said:

"Indeed, it is not too much to say that a denial to Congress of the right, under the Constitution, to delegate the power to determine some fact or the state of things upon which the enforcement of its enactment depends would be 'to stop the wheels of Government', in the conduct of public business."

Advertising, regulation by Federal Trade Commission.—If I may, with propriety, refer to the recommendations of the proprietary-medicine manufacturers, the spokesman for certain advertising media, and the Chairman of the Federal Trade Commission, to assign to that organization the enforcement of the advertising provisions of the act, I will say that I am more concerned in the enactment of a law whose terms are adequate for the protection of the consuming public than I am the designation of the governmental body by which it will be enforced. I urge that there be no division of responsibility in the control of adulteration, misbranding, and false advertising of food, drugs, and cosmetics. These three offenses are too intimately interwoven to permit effective treatment separately. The briefest of administrative experience is sufficient to condemn divided administrative authority. Such an arrangement presumes continued harmonious cooperative relationship which cannot possibly exist indefinitely. Any impairment of such relationship will be reflected in the inefficient enforcement which will inevitably result. If the Federal Trade Commission is qualified to administer this law more satisfactorily than the Food and Drug Administration, transfer all phases of its enforcement to that body. As a preliminary to such action I urge also that modification be made of the procedure imposed on it in the act for regulation of trade practices. The issuance of orders to cease and desist is not sufficient to suppress false advertising or to prevent the marketing of adulterated and misbranded articles. So long as an offender realizes that he is free from a visitation of penalties until after he shall have received an invitation to desist, there will be a total absence of incentive voluntarily, through fear or otherwise, to comply with the law. There is need for the exercise of a deterring influence.

Voluntary inspection.—Senate 5, like its immediate predecessor S. 2800, contains no provision of the kind found in S. 1944 authorizing the Department to extend supervisory inspectional services to manufacturers desiring such services and willing to acquire it at their own expense. This provision is primarily of interest to manufacturers anxious to extend consumer goodwill through assurances that preparation of their product has been supervised by representatives of the Food and Drug Administration. Similar service by other Federal agencies has for several years been provided by Federal statute. This feature of the initial measure met with instant and almost unanimous opposition. But within less than 1 year from the date of the hearing, an amendment to the Food and Drugs Act was passed authorizing the Secretary to formulate regulations for the extension of supervisory inspection to the shrimp-canning industry. This legislation was advanced and supported by that industry exclusively. Its enforcement has effectively eliminated the canning of decomposed shrimp. Our interest in seeing an extension of this authorization to other than sea-food industries is dictated by a recognition of the very definite improvement in the quality of food which it effects. This is of benefit to the public. No amendment to the bill on this subject is offered. This comment is preliminary to an expression of the hope that at some time, through independent legislation perhaps, appropriate legislation will be enacted.

Standards of quality.—Senate 1944 authorized the promulgation of standards of quality or grades. In both S. 2800 and S. 5, provision for the establishment of standards of quality has been eliminated except for the extension of the McNary-Mapes canned-food amendment of the present law to all food products. This amendment provides for the determination of a single standard of quality, with the requirement that substandard articles be so labeled. Such substandard products ordinarily are not to be found in the retail market. They are disposed of through sales to institutions. This amendment, therefore, is of negligible value in the promotion of discriminatory buying, so far as the individual consumer is concerned. Since standards of quality for a great many food products will, if made effective only after deliberate determination of the factors upon which such standards should depend and after the extension of sufficient information on this point to both producers and consumers, operate to the advantage of both, it is to be regretted that no provision for the establishment of such standards is carried in this bill. No recommendation is being made for the addition of a paragraph to that effect. The present controversial character of the question is fully realized. To amend the measure by including authorization for promulgation of standards of quality would undoubtedly operate to delay, if not defeat, the passage of the bill. It is to be hoped that at some future time, by special measure, this question will receive further legislative consideration. Meanwhile this bill contains too many splendid provisions for a vast increase in the protection of the public over what can be afforded by the present law to encourage the advancement of a proposal for any amendment of it which might operate to delay its passage.

APPLECROFT EXPERIMENT STATION,
GREENLAWN, LONG ISLAND,
Friday, March 8, 1935.

In re Senate bill 5:

Senators Clark, Copeland, and gentlemen of the committee, my name is Mrs. Christine Frederick, of 80 West Fortieth Street, New York City.

I am a home economist, a consumer consultant, author of "Selling Mrs. Consumer", and the household editor of the American Weekly.

I am addressing you on behalf of Advertising Women of New York, Inc.

Advertising Women of New York, Inc., is an organization of several hundred business women, a great number of whom are engaged in the fields of drugs, foods, and cosmetics.

I am a member of this organization because I feel that all women engaged in studying the consumer's interests should be more closely associated together.

The interests of the consumer and of the modern honest advertiser are fundamentally the same. The advertiser profits by serving the best interests of the consumer, and the woman consumer profits by patronizing those advertisers who operate high-grade policies. Advertising women are also women consumers and their aim is to deserve and win the consumer's patronage. Advertising Women of New York, Inc., are definitely committed to truthful, intelligent advertising appeals and informative labeling.

It is for this reason that Advertising Women of New York, Inc., wishes to go on record as sincerely in favor of pending Senate bill S. 5 as sponsored by Senator Copeland.

Moreover they feel that there is no logical reason why the Department which now has power over labeling and adulterations should not also have power over advertising, since this is only an extension of the preceding. Hence they desire to express themselves as wishing the administration of this pending bill to be vested in the Department of Agriculture, which has for the past 30 years so successfully dealt with cases involving foods, drugs, and cosmetic products.

I thank you for permitting me to express these sentiments of Advertising Women of New York, Inc., and congratulate you on this progressive measure which we hope will speedily be enforced.

[Telegram]

PHILADELPHIA, PA., *March 7, 1935.*

Hon. R. S. COPELAND,
Senate Office Building:

Will you please include in your record of the hearing on bill S. 5 to be held tomorrow, Friday, March 8, at 10 a. m., the following resolution of our organization: "The Philadelphia Club of Advertising Women, 158 members, registers approval of bill S. 5 and wishes it passed as quickly as possible. Please include this request in the record of the hearing."

NAN M. COLLINS, *President.*

THE ASSOCIATION OF DAIRY, FOOD, AND DRUG OFFICIALS OF THE UNITED STATES,
March 5, 1935.

Hon. BENNETT CHAMP CLARK,
Chairman Subcommittee, Senate Committee of Commerce,
Senate Office Building, Washington, D. C.

DEAR SIR: With reference to a bill introduced in the Congress, S. 5, commonly referred to as the "Copeland bill", that has as its purpose a revision of the Federal Food and Drugs Act, may we respectfully call your attention to the interest and action of the Association of Dairy, Food, and Drug Officials of the United States at former annual conferences with reference to proposed Federal legislation that may affect so vitally the work of individual States?

This association, the membership of which is made up of active regulatory law enforcement officials engaged in work pertaining to dairy, food, and drug products in the States, counties, and cities, at one time carefully considered and approved Senate bill 1944 which had as its object the complete revision and substitution for the present Federal Food and Drugs Act, and adopted a resolution to this effect, in the following language:

"Whereas, in accordance with the report of the special committee appointed to consider proposed amendments to the Federal Food and Drugs Act known as 'Senate bill S. 1944'; and

"Whereas it is believed that if this bill is enacted into law it will be of great assistance to the State and municipal officials in the enforcement of State food and drug laws; and

"Further, as is evidenced by the expression of opinion regarding this particular measure of strengthening the national control: Therefore

"*Be it resolved*, That this association unanimously endorse this bill and urge its prompt enactment into law:

"*Be it further resolved*, That the President appoint a committee of three to bring this resolution to the attention of the Secretary of Agriculture, the Honorable Henry C. Wallace, and that this committee also urge officials concerned to render such assistance as is possible in bringing about the final enactment of this bill."

S. 1944, we understand, was later superseded by S. 2800. The latter made certain major changes that did not appear in S. 1944. The Association of Dairy, Food, and Drug Officials of the United States never considered nor expressed an opinion as an association with reference to S. 2800. The basic changes that appeared in S. 2800 would obviously concern a majority of the food laws now in force by a great many States, if not bring the State activities in direct conflict with other programs.

Particularly was this true with reference to the standards committee, provided for in S. 2800. In S. 1944, standards were fixed, established, and promulgated by the Secretary of Agriculture.

From a consideration of S. 5, that has been introduced and printed and is now before your committee for consideration, the executive committee of this association views with alarm the lack of representation on the Food Standards Committee of State officials.

Through a great number of years representatives of the State Food and Drug Officials' Association have had representation on the Food Standards Committee of the Federal Department of Agriculture.

The fact that State laws now generally in force compel State officials to proceed under regulations and announcements of the Secretary of Agriculture and require the States to adopt as their standard food standards promulgated by the Federal Department of Agriculture, makes obvious that a fair representation of regulatory officials from States should be provided for in the matter of establishing standards, which State officials, inevitably under the terms of their own State laws, would be compelled to follow and adopt.

Under the present set-up and cooperation of State officials, working with the Federal Department of Agriculture, there has for many years grown up to a great degree uniformity of food standards throughout the country, the formation of which standards have been the joint work of the Federal Department of Agriculture, representatives of the Association of Dairy, Food, and Drug Officials of the United States and representatives from the Association of Official Agricultural Chemists.

We respectfully request, therefore, that due consideration be given to include in the provisions of the proposed enactment to regulate food, drug, and cosmetic industries, definite requirements as to the personnel of the Food Standards Committee, to include representation of State food officials to the end that uniformity of purpose and action that now prevails will not be destroyed, and that industry will not be subjected to the authority of innumerable State enactments, which in the end would defeat the very purpose for which this legislation is intended.

If we can furnish you any additional information or facts, we are at your command.

Sincerely,

W. C. GEAGLEY, *Secretary-Treasurer.*

E. R. SQUIBB & SONS,
New Brunswick, N. J., March 4, 1935.

Hon. ROYAL S. COPELAND,
United States Senate Office Building, Washington, D. C.

MY DEAR SENATOR: In accordance with the telegram previously sent you, we are sending you two copies of statement signed by me on behalf of E. R. Squibb & Sons, in which the position of E. R. Squibb & Sons is set forth concerning S. 5.

We wish to supplement the statement in the comments sent herewith concerning the matter of transfer of the regulation concerning advertising other than on the package from the Food, Drug, and Insecticide Administration to the Federal Trade Commission.

We think that such transfer would be highly inadvisable not only from an administrative standpoint, but we are inclined to believe also from the standpoint of those who may become subject to the provisions of the law.

We therefore hope that the entire administrative control of the act will be vested in a single bureau.

Faithfully yours,

E. R. SQUIBB & SONS,
JOHN F. ANDERSON,
Vice President.

[Telegram]

MARCH 2, 1935.

Hon. ROYAL S. COPELAND,
United States Senator,
Senate Office Building, Washington, D. C.

On behalf of E. R. Squibb & Sons I wish to record our strong approval of S. 5, committee reprint no. 3, as a desirable and effective improvement of the present Federal laws governing the sale of drugs, medicinal preparations, and similar products. We have given the bill in its present form careful study, and we are forwarding a short statement, based upon our analysis, which expresses our approval of the bill, together with certain specific suggestions for improving the current draft. The suggestions we have made are not extensive, but we believe are worthy of the attention by the committee. May I ask that you arrange that our statement is placed before the committee dealing with the bill? Aud if you wish to place the contents of this telegram before the hearings on the bill now being held by Senator Clark's subcommittee, you are, of course, at liberty to do so.

Dr. JOHN F. ANDERSON,
Vice President.

To the Committee on Commerce of the United States Senate:

E. R. Squibb & Sons have given very careful consideration to the food, drug, and cosmetics bills which have been introduced in the first session of the Seventy-fourth Congress. Of these bills, it is our conclusion that the so-called "Copeland bill", S. 5, with certain modifications that we deem to be of a minor character when compared with the bill as a whole, contains the best means of checking practices in connection with the sale of food, drugs, and cosmetics which now actually endanger the public health, as well as impose upon the consumer. Although bills such as H. R. 3972 and S. 580 contain many provisions which constitute a great advance in food, drug, and cosmetic legislation and would undoubtedly materially assist the Food and Drug Administration of the Department of Agriculture in checking abuses which are now current, our examination of the bills convinces us that the Copeland bill is better designed to accomplish the purposes desired than any of the other bills thus far introduced. It represents the result of the consideration which was given to the original Copeland bill introduced in the Senate last year, and perhaps more than any other bill reflects the opinion of your committee and the Food and Drug Administration itself as to the type of legislation necessary to enable that Administration to function efficiently. We do not believe that the recommendations of the Food and Drug Administration are or should be the sole considerations in determining the merits of the bill, but in our view the recommendations of that Administration are extremely important. S. 5, Committee Print No. 3, represents a very material improvement of the original Copeland bill, S. 1944, and with certain simple modifications we believe that it can well be accepted by the industries concerned as an effective and just means of eliminating dangerous and unfair practices with which the present Food and Drug Act is not competent to cope.

We definitely do not favor the introduction of the Federal Trade Commission into the regulation of this field. In our view, such introduction would only result in dual and perhaps conflicting control and added expense both to the Government and the industry.

The suggestions which we make for the modification of S. 5, Committee Reprint No. 3, are not many and are sincerely put forward as a method of improving the bill.

Before passing to our suggestions in detail, we wish definitely to record the fact that we trust that your committee will favorably report S. 5, Committee Print No. 3, to the Senate in what we consider to be substantially its present form.

MISBRANDED FOOD

Section 302 (j), page 9, lines 3 to 9, inclusive, reads as follows:

"SEC. 302. A food shall be deemed to be misbranded—

* * * * * * *

"(j) If it purports to be or is represented for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by regulations as provided by sections 701 and 703, statements concerning its vitamin, mineral, and other dietary properties which *fully* inform the purchaser as to its nutritional value." (Italics ours.)

We recommend the omission of the word "fully" in line 8. In our opinion, the public will be adequately protected with the omission of such word, since any statements made which are not adequate would not really "inform the purchaser." It is only when the information given in branding a product is material or immaterial that the adequacy of the branding should be determined. The use of such a word as "fully" immediately introduces questions which have given rise to great uncertainties in other regulatory legislation. The use of such word in this bill would make it necessary, in order for the manufacturer to safeguard himself, to introduce much irrelevant material in his branding. By reason of restriction of space, this compels resort to "fine print" and lengthy statements which may obscure rather than enlighten the consumer. We believe that the use of the word "fully" in the section above referred to, although apparently helpful to the consumer, does not therefore really accomplish the desired result.

ADULTERATED DRUGS

Section 401, page 15, line 8.

Manufacturers of ethical medical preparations strongly feel that it is eminently unfair to place the stigma of adulteration upon their products merely because certain drugs produced by them which unavoidably are liable to deterioration may subsequently be found, sometimes years after their sale, to be below their original standard. These manufacturers have no objection to the designation of such drugs as deteriorated; but when, through absolutely no fault of their own, these drugs fall below standard strength, they should not be designated as adulterated, which designation carries with it, at least to the public, implications of deliberate or careless acts. Accordingly, in order to avoid stigmatizing these products as adulterated, we strongly recommend the insertion of a new paragraph, beginning at line 8, page 15, reading as follows:

"Any provision in this Act to the contrary notwithstanding, however, a drug shall be deemed to be adulterated only for reasons other than any deterioration in potency thereof occurring after its introduction into interstate commerce."

There is no reason, however, why a drug which has become deteriorated in potency after its introduction into interstate commerce should not be liable to be proceeded against to the same extent as an adulterated food, drug, or cosmetic. Provision may be made for stopping products in interstate commerce which have become deteriorated without designating them as adulterated, and this should satisfy both the purposes of the Food and Drug Administration and the very reasonable sensibilities of the manufacturer. This can be accomplished by amendment to section 711 (a), page 41, line 23, which now reads in part as follows:

"SEC. 711. (a) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found."

After the word "into", insert a comma in place of the word "or"; and after the words "while in", insert the following:

", or that has deteriorated in potency after its introduction into".

The above-mentioned language will then read as follows:

"SEC. 711. (a) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into, while in, or that has deteriorated in potency after its introduction into, interstate commerce * * * shall be liable to be proceeded against while in interstate commerce or at any time thereafter on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found."

With the above-mentioned amendment to section 711 (a), the public will be fully protected from drugs which have become deteriorated in potency after leaving the manufacturer. At the same time the above-mentioned amendment to section 401 avoids the unnecessary stigma which would result from libeling such a drug as adulterated.

MISBRANDED DRUGS

Section 402 (e), page 16, lines 20 to 25, inclusive.

E. R. Squibb & Sons heartily approve section 402 (e) as it now appears in S. 5, Committee Print No. 3, requiring the disclosure of the active ingredients of a product. There is no reason why the public should not know what ingredients are contained in the products which it buys. Such disclosure will aid materially in reducing the number of false representations with respect to the merit and effect of drugs.

ADULTERATED COSMETICS

Section 501 (a), page 20, line 22, to page 21, line 3, inclusive, provides as follows:

"SEC. 501. A cosmetic shall be deemed to be adulterated—

"(a) If it bears or contains any poisonous or deleterious substance which *may* render it injurious to health under the conditions of use prescribed in the

labeling or advertising thereof, or under such conditions of use as are customary or usual." (Italics ours.)

The inclusion of the word "may" before the word "render" has the effect of designating a cosmetic as adulterated, even though the conditions of its use as prescribed in the labeling would be perfectly safe for all but a bare few persons who might possess particular idiosyncrasies for that cosmetic. At the same time the use of such words injects the element of uncertainty and speculation. We believe that it would be much more certain and at the same time entirely sufficient for the purposes of the bill to amend subdivision (a) merely by omitting the word "may" so that the subdivision will read as follows:

"(a) If it bears or contains any poisonous or deleterious substance which renders it injurious to health under the conditions of use prescribed in the labeling or advertising thereof, or under such conditions of use as are customary or usual."

Since the use of the word "may" has been eliminated in the corresponding provisions dealing with the adulteration of drugs (see sec. 4 (a) of S. 1944), we believe the corresponding change should be made here and for the same reasons.

This completes our suggestions with respect to S. 5. We have examined the general administrative provisions of the proposed bill, and although they grant extensive powers which have not heretofore reposed in the Government and in some cases may enable multiple seizures to be made, we believe there are sufficient safeguards against arbitrary action on the part of officials of the Department to warrant the manufacturer in believing that his legitimate interest will not be unduly prejudiced by the enactment of these sections of the bill.

Respectfully submitted.

E. R. SQUIBB & SONS,
JOHN F. ANDERSON, M. D.,
Vice President.

ALBERS DRUG CO.,
Knoxville, Tenn., February 27, 1935.

Hon. BENNETT CHAMP CLARK,
Senate Committee on Commerce,
Washington, D. C.

DEAR SIR: With reference to food and drug legislation, now pending, and on which hearings are to be held before the Senate Committee on Commerce, Saturday, March 2.

We submit and urge your serious consideration of important fundamentals as outlined on the attached memorandum.

Yours very truly,

ALBERS DRUG CO.,
EDW. S. ALBERS, *President.*

[Memorandum]

1. We believe that multiple seizures should not be imposed upon the industry except for adulteration or for serious misbranding and then (on court order) where it is necessary to protect the public. Adulteration is usually subject to actual determination. Misbranding on the other hand is often a matter of opinion.

2. We believe that the most far-reaching and effective protection to the public against false advertising should be obtained through the procedure of (*a*) hearings in the Department of Agriculture, (*b*) Federal Trade Commission proceedings, and (*c*) court injunctions. The machinery is all ready set up for this method. Experienced and well-qualified men are now actually engaged in this work and have been for several years. This procedure would not call for materially increased appropriations.

TERPEZONE, INC.,
Chicago, March 6, 1935.

Senator BENNETT CHAMP CLARK,
Senate Office Building, Washington, D. C.

HONORABLE SIR: I testified before the committee conducting drug-bill hearings last year and have already written you for appointment to appear again this year. While some of my testimony would be repetition, which you naturally wish to avoid, still I believe that we are entitled to make an emphatic protest against the passage of legislation that could only destroy a meritorious product. This in itself would not be so bad except that it destroys the hope of sufferers of disease who cannot be aided by medicine.

1. We object to the definition of "drugs", as our product is an electrical device, taking outdoor air and stepping up the oxygen content of a room.

2. An opportunity should be extended for hearings before criminal action is taken by the Government.

3. "Single" seizures should be ample to decide the merits of a case.

4. The most insidious part of the entire bill is the power of the Secretary to prescribe a list of diseases which it will be against the law to mention in connection with advertising. The board of reviews will be composed of members of the American Medical Association, who are notorious in their antagonism to commercial products dealing with health.

We submit that if the bills were separated and the public could be given time to be educated as to the intentions back of the drug bill, that it would be defeated, and we further submit that it is possible to attain purity of foods, drugs, and cosmetics without necessity for such drastic legislation that will force honest business to close its doors. It is inconceivable that such a bill could be seriously considered by the Congress who are considering measures that will help recovery. The bill is definitely the extension of a medical monopoly, whose medical opinion changes from day to day.

The discoverer of Terpezone was William John Knox, who studied at the University of Michigan, and in their year book they comment on his discovery of a well-known oil-cracking process. He was a famous chemist like Pasteur, whose original discoveries were also ridiculed by the medical powers.

We had expensive litigation, and a high court decided, in the face of all the medical testimony submitted, that Terpezone was not a medicine or drug, and a bill that would term this conditioned "air" a "drug" is not just and would work a great harm. We hope that you will file this protest.

Respectfully yours,

TERPEZONE, INC.,
F. L. ROGERS, *President.*

FEDERAL WHOLESALE DRUGGISTS ASSOCIATION, INC.,
Washington, D. C., March 2, 1935.

Hon. BENNETT CHAMP CLARK,
Chairman Subcommittee Senate Commerce Committee,
Washington, D. C.

DEAR MR. CHAIRMAN: The Federal Wholesale Druggists Association, distributing drugs and medicines and other drug-store merchandise to no less than 12,000 retail druggists—stockholders and customers—desires to be recorded as in favor of H. R. 3972, introduced by Representative Mead, of New York.

Its executive officers have reached the conclusion that this bill will best accomplish the purpose of safeguarding the public health and welfare by amending the existing law so as to meet modern requirements after carefully following the analyses of the various bills pending before Congress.

This association was not prompted by any desire to favor any one particular group of manufacturers in deciding to support the Mead bill. It was prompted solely by considerations in the interest of the public and the drug industry, including the advertising and distribution of drugs and medicines. It is sincerely believed that the Mead bill will properly and adequately perfect the existing law so as to protect the public in exercising its right of self-medication without unduly working a hardship on drug manufacturing, wholesaling, retailing, and advertising.

The Mead bill is simple and plain in its provisions and therefore less susceptible to misinterpretation and misapplication in its administration if it should become a law. This is highly important from the viewpoint both of the interest of the public and industry.

Finally, it is sincerely believed that the Mead bill conforms substantially to the following fundamental principles which should underlie any new legislation:

1. The drug industry now takes an affirmative position for the enactment of food, drug, and cosmetic legislation at this session of Congress for the proper safeguard and protection of the public and of a character not to impose an undue hardship upon legitimate industry.

2. It is the sense of the drug industry that modernizing amendments because of decisions of Federal and State courts are preferable to an entirely new law.

3. Resolved that the industry believes:

(*a*) That multiple seizures should not be imposed upon the industry except for adulteration or for serious misbranding, and then on court order only where necessary to protect the public;

(*b*) In all other cases single seizures only should be imposed.

4. We believe that the most far-reaching and effective protection to the public against false advertising should be obtained through the procedure of (a) Federal Trade Commission proceedings and (b) court injunctions. The machinery is already set up for this method. Experienced and well-qualified men are now actually engaged in this work and have been for several years. This procedure would not call for materially increased appropriations.

5. Obligations and prohibitions pertaining to control of matters involving public health and welfare should be specifically set forth in the law and not left to departmental regulations.

We do not think that there can be any disagreement as to the soundness of the foregoing underlying principles.

Respectfully submitted.

HARRY Z. KRUPP,
President.
R. E. LEE WILLIAMSON,
Secretary.
E. C. BROKMEYER,
General Counsel.

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS,
Washington D. C., March 8, 1935.

STATEMENT OF NATIONAL ASSOCIATION OF RETAIL DRUGGISTS ON S. 5, COMMITTEE PRINT 111

To Members of the Subcommittee,
Committee on Commerce, United States Senate, Washington, D. C.

GENTLEMEN: It is with a great deal of pleasure that I am able to inform you at this time, that the National Association of Retail Druggists, composed of 20,000 independent pharmacists, lends its active support to the high purposes of the legislation contemplated by S. 5, committee print 111.

The retail pharmacist has in the past been cognizant of the evils and abuses which make the passage of corrective legislation imperative today in the interest of the public health. The National Association of Retail Druggists condemns without qualification all false and fraudulent statements made on the labeling or in the advertising of any drug, cosmetic, or food. We subscribe in full to the advertising, adulteration, misbranding, and enforcement provisions of this bill with the minor exceptions hereinafter noted. We take the position that ours is a public-health profession, that there is reposed in the pharmacists of this country a public trust, and that we are obligated to support any legislation which may be reasonably expected to be of public benefit.

In general, we are distrustful of government by departmental regulation, order, or dictum, but we also feel that in problems of this kind some leeway must be granted in this respect in order to carry out the purposes of this legislation.

As a result of this distrust, we submit the following recommendation: Provision should be made in this bill to prevent publicity being given to actions brought under the various sections of this bill until such time as conviction is obtained. The provisions of this legislation are so broad and sweeping that a large variety of innocent violations are bound to occur, particularly during the first year or two after the effective date. Individuals or firms might be irreparably damages if publicity were given to actions taken by the administration even though no bad faith could be proven. We hold no brief for deliberate or habitual violators of the provisions of such legislation as this, but we feel that innocent parties, acting in good faith, may be damaged by publicity prematurely given. We urge that a section be added to this bill to take care of such situations.

We reserve the right to oppose any changes, additions, or deletions which may be made in this bill.

Respectfully,

ROWLAND JONES, Jr.,
Washington Representative.

AMERICAN BOTTLERS OF CARBONATED BEVERAGES,
Washington, D. C., March 5, 1935.

Hon. ROYAL S. COPELAND,
United States Senate Office Building, Washington, D. C.

MY DEAR SENATOR: The American Bottlers of Carbonated Beverages, which is the national trade-association representative of the bottled-soft-drink industry, endorses bill S. 5 as originally presented by you.

It is regretted that due to a general meeting of our board we are not able to present our case by word of mouth. However, we wish that you would have this letter read into the record as an indication of our attitude.

Yours very truly,

AMERICAN BOTTLERS OF CARBONATED BEVERAGES,
JAMES L. OLIVER, *Secretary.*

MANUFACTURING CHEMISTS' ASSOCIATION OF THE UNITED STATES,
Washington, D. C., March 13, 1935.

Hon. BENNETT CHAMP CLARK,
Chairman Subcommittee of Senate Committee on Commerce,
Senate Office Building, Washington, D. C.

MY DEAR SENATOR CLARK: Enclosed herewith is a brief submitted on behalf of the Manufacturing Chemists' Association on S. 5.

Very truly yours,

W. N. WATSON.

BRIEF OF THE MANUFACTURING CHEMISTS' ASSOCIATION OF THE UNITED STATES

Pursuant to public notice of hearing on S. 5, we appear today as representatives of the Manufacturing Chemists' Association of the United States, an organization established in 1872, and comprising the leading chemical manufacturers of this country.

The relationship of the members of this association to the public health, national industry, and national agriculture must be clearly borne in mind. The chemical products of these manufacturers are utilized in the alleviation of pain and suffering and in the control of disease; in the preparation of foods and beverages and other consumptive goods; and in the protection of agriculture against vegetable and insect parasites. In each of these fields our members have an extensive and continuous research program.

Appreciative of the importance of general health and the public welfare, and after close and impartial study of the conditions which now obtain in the fields covered by the Food and Drug Act, we are led to the belief that the law now in force requires amendment or revision.

Member companies have made a careful analysis of S. 5 and we respectfully submit the following amendments which, although relatively few in number and not in conflict with the fundamental objectives of the bill, we are deeply convinced are of the utmost importance and should be adopted.

Provision should be made in S. 5 for idiosyncrasy in order to protect the seller and maker from claims due to supersensitive reaction of a few individuals.

Chapter IV. Section 401. Idiosyncrasy.—Add the following provision:

"*In construing and enforcing section 401 a reasonable allowance shall be made for idiosyncrasy or supersensitivity to the use of a drug.*"

Section 401 (b), page 11, line 16 on: Revise and amend as follows:

(b) If its name is ~~the same as or simulates a name~~ recognized in an official compendium, or if it purports to be a drug the name of which is so recognized, and it ~~(1) fails to meet the definition and description set forth therein or~~ (2) differs from the standard of strength, quality, identity, or purity as determined by the tests or methods of assay set forth therein; except that whenever tests or

methods of assay have not been prescribed therein, or such tests or methods of assay as are prescribed are insufficient, for determining whether or not such drug complies with such standard, the Secretary is hereby authorized to bring such fact to the attention of the appropriate body charged with the revision of such compendium and if such body fails within a reasonable time to prescribe tests or methods of assay which are sufficient, then the Secretary may prescribe for the purposes of this act such tests or methods of assay by regulations as provided by sections 701 and 703. No drug shall be deemed to be adulterated under this paragraph ~~because it differs from~~ if the standard of strength, quality, identity, or purity ~~therefor set forth in an official compendium, if~~ be plainly stated on its label although the standard may differ from that ~~bears in juxtaposition with the name of the drug a statement indicating wherein its strength, quality, and purity as~~ determined by the tests or methods of assay ~~applicable under this paragraph, differ from the standards therefor~~ set forth in an official ~~such~~ compendium. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

Section 402 (a), page 13, line 8: Revise the phrase "in any particular" so that it reads "in any essential particular."

Section 402 (a), page 13, line 11: Revise the phrase "in every particular" so that it reads "in any essential particular."

Failure to incorporate this revision would retard and prevent improvements and developments.

Section 402 (f), page 15, line 1–13.

A drug shall be deemed to be misbranded * * * (f) If its labelling fails to bear plainly and conspicuously (1) complete and adequate directions for use * * *.

We submit that, as drawn, this section would require: First, every package of medicinal chemicals and drugs to be labelled so as to show complete and adequate directions for use;

(1) So-called "subdivisions", i. e., ⅛ ounce and smaller to 5 pounds intended for sale ultimately to the pharmacist for use in compounding physicians' prescriptions.

(2) Bulk packages, from 10 pounds to and including barrels, intended for sale to manufacturers of pharmaceutical, proprietary remedies, medicines, and the like.

Second, certain drugs and chemicals are recognized as specific treatment for specific ailments. On the other hand, these and countless others have applica- differs from the standard of strength, quality, identity, or purity as determined purposes of this act such tests or methods of assay by regulations as provided by tion in many conditions of illness.

(1) The dosage or directions would vary with the indications; for example, potassium iodide is employed as a diuretic, antirheumatic, antisclerotic, and in prescriptions for such uses the dosage would vary with the condition of the ailment, the patient, the type of treatment. Another example: Quinine sulphate is indicated for tonic use in dosage of 1½ grains, while for antimalarial medication, the dosage varies up to 15 grains; quinine has over 30 uses in addition to its use in malaria.

(2) It is obviously impracticable to label such packages with directions for use in respect to all conditions in which the drug or chemical is indicated.

(3) It is obviously impossible to label small packages, say ⅛ ounce to 1 ounce, with adequate directions for use in respect to all conditions in which the drug may be indicated;

Third, there are certain drugs and chemicals not described in the official compendium, being newly developed and yet having a recognized use, which would, by reason of paragraph (f) be required to be labelled as described above, and concerning which the same conditions would exist as described in the paragraph marked "Second" above.

In view of the matter set forth above we respectfully recommend:

1. A provision in section 402 (f) exempting U. S. P., N. F. and U. S. H. P. official preparations, or

2. A provision exempting drugs and chemicals (in all sizes of packing up to and including largest bulk sizes) when sold to other consumers than the lay public.

Section 402 (j), page 16, line 17: Delete "or antiseptic" and substitute therefor "germicide, bactericide, or disinfectant for any use."

The test of germicidal effect should not be restricted to the phenol test, as this is applicable only to phenolic bodies and its enactment in a statute would prevent scientific progress.

Section 402 (k), page 17, lines 8 and 9: To be changed to: "If it purports to be or is represented to be an antiseptic for any use."

Section 501, page 18, adulterated cosmetics: Insert a new provision in section 501 to read:

"In construing and enforcing section 501 a reasonable allowance shall be made for idiosyncrasy or supersensitivity to the use of a cosmetic."

Section 502 (a), page 18, line 24: Revise the phrase "in any particular" so that it reads "in any essential particular."

Section 503 (a), page 20, line 3: Refer to the phrase "may be injurious to health." Provision should be made to exempt idiosyncrasy from this section.

Section 601 (a), page 20, line 17: Revise the phrase "in any particular" so that it reads "in any essential particular."

Section 601 (a), page 20, line 20: Revise the phrase "in every particular" so that it reads "in any essential particular."

Section 703 (a), page 23, line 5: Strike out "five" and insert "seven." And provision in line 8 that said committee shall include a chemist, pharmacist, pathologist, veterinarian, and a dentist.

Section 704, page 26, line 14: Strike out "is authorized to" and substitute "shall." This makes it mandatory for the Secretary to appoint an advisory committee, whereas under the present language it is optional to appoint an advisory committee.

Section 708 (a), page 30, subparagraph (6), lines 6 to 9: The section 305 referred to in subparagraph (6) refers only to foods, whereas subparagraph (6) on page 30 refers to food, drug, or cosmetic. In line 7 "drug or cosmetic" should be stricken out in order to make it consistent with section 305.

Section 711 (c), page 36, lines 8 to 10: Insert after the word "seized" the phrase "and also the method used for testing of said sample."

The industry represented in this association has initiated and sponsored amendments to the present law in the course of its 28 years of administration and is familiar with the conditions with respect to which the law is unresponsive. We are of the firm belief that the present law can be satisfactorily amended. We earnestly seek the opportunity to lend our assistance, through the best scientific and professional minds of the chemical industry, in meeting with the subcommittee in the endeavor to draft amendments to the present bill which will effectually carry out the purposes of the Congress to legislate for the benefit of the general health of the people and for the public welfare.

NORTHWEST CANNERS ASSOCIATION, INC.,
Portland, Oreg., February 18, 1935.

Hon. CHAS. L. MCNARY,
United States Senate, Washington, D. C.

DEAR SENATOR MCNARY: When I was in Washington recently I spoke to you briefly regarding Senator Copeland's bill, S. 5, which is a revision of the Food and Drug Act. I stated to you that we were generally in accord with the act but would present some few amendments.

I am now advised that amendments have been presented through Senator Copeland—all have been approved by him and have been inserted in a reprint of the bill. This simplifies the proceedings so far.

The thing that now worries us is that the Department of Agriculture will probably request amendments covering grade labeling and voluntary inspection, and we are definitely opposed to any form of Government A, B, C labeling. In the Northwest this would be particularly bad for the reason that we have built up very high standards of quality and they are really superior to any other part of the country. If the Government should put in a grade A, B, C ruling, then the grade A, for instance, would have to be sufficiently broad to allow all sections of the country to pack under it. This would require a low level and not a high level, because others simply haven't the fruit that we have. Therefore, we would be placed in the position of giving up what we have so lately

earned through our improvement in growing fruit and in packing, and it certainly would lead to inferior packing out here instead of superlative packing.

I note that the districts that are strongly in favor of this ruling are the districts that do not produce quality fruits and vegetables, and I don't blame them, of course, but you can easily see that it would be a tragedy for us.

We believe that on informative labeling the labels should tell what is in the can, but don't think A, B, C is any improvement on present conditions—if anything, it is worse, because under present conditions you could at least buy by brand name and be assured of your quality, whereas, as pointed out above, a straight grade A across the country would mean the lowest possible standard for an A grade and nothing more.

With kindest regards.

Yours truly,

NORTHWEST CANNERS ASSOCIATION, INC.,
E. M. BURNS, *Secretary.*

PACIFIC DRUG REVIEW,
Portland, Oreg., February 19, 1935.

Sen. C. L. MCNARY,
Senate Office Building, Washington, D. C.

DEAR SENATOR MCNARY: We recently wired you a protest against the Copeland bill in its present form and acknowledge your response thereto.

Now, we would like to put into your hands some of the objectionable features of the Copeland bill as viewed by the proprietary interests. We quote below four paragraphs taken from a letter which we have just received which points out some of the objectionable features:

1. It is another of the skeleton bills which attempts to leave most of the interpretations, rules, regulations, and in many instances completion of the law itself, to the Secretary of Agriculture, who is practically granted czaristic power.

2. It places the control of food, drug, and cosmetic advertising in the hands of the Food and Drug Administration, a Department which has no experience in controlling advertising, and takes it away from the Federal Trade Commission who have successfully handled all types of advertising for years. Advertising is a commercial function and not agricultural.

3. It attempts to change the terms "false and fraudulent" of the present act, to the all-encompassing and indefinite terms "false or misleading in any particular." Our courts have already decreed that fraud must clearly show "intent to deceive." This new provision contemplates a latitude in direct contradiction to, and far beyond the fundamentals laid down by, the court itself. Under such a provision the Department, in the light of its attitude of the past, could prevent every piece of advertising copy in America. We will all normally disagree as to what is clear and what is misleading.

4. It allows in professional journals the type of advertising which it calls false and misleading, and which it forbids in newspapers, magazines, and radio. This provision, so prominent in the Tugwell bills of the past, has already many medical advertisers to curtail commercial advertising and emphasize the ethical exclusively. Some have withdrawn from the domestic field and are concentrating sales and advertising efforts in foreign countries. This has already resulted in a drop in lineage of national advertising. It is unfair in the extreme.

The proprietary medicine business is an immense industry. It should be under some regulation and undoubtedly the present pure food and drug law needs some straightening but we do not believe there is any occasion to let the bars down to interpretations, rules, and regulations by the Secretary of Agriculture which might be injurious to this great industry.

As a matter of fact, we believe that any bill which is written should be specific and not filled with generalities nor subject to several interpretations nor do we believe it should allow much, if any, scope to any department of the Government to regulate an industry beyond the provisions of the bill itself.

May we ask that you give careful consideration to this bill and particularly to the objections noted above? Not only is the bill in its present form injurious to the manufacturing industry, but we believe it would also be seriously injurious to distributors of proprietary remedies such as retail druggists, etc.

Sincerely yours,

F. C. FELTER, *Manager.*

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TITLE